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Code of Federal Regulations

42

Parts 400 to 429

Revised as of October 1, 2005

Public Health

Containing a codification of documents of general applicability and future effect

As of October 1, 2005

With Ancillaries

Published by
Office of the Federal Register
National Archives and Records
Administration

A Special Edition of the Federal Register

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Cite this Code: CFR

To cite the regulations in this volume use title, part and section number. Thus, 42 CFR 400.200 *refers to title 42, part 400, section 200.*

Explanation

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16.....as of January 1
Title 17 through Title 27.....as of April 1
Title 28 through Title 41.....as of July 1
Title 42 through Title 50.....as of October 1

The appropriate revision date is printed on the cover of each volume.

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The Paperwork Reduction Act of 1980 (Pub. L. 96–511) requires Federal agencies to display an OMB control number with their information collection request.

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Provisions that become obsolete before the revision date stated on the cover of each volume are not carried. Code users may find the text of provisions in effect on a given date in the past by using the appropriate numerical list of sections affected. For the period before January 1, 2001, consult either the List of CFR Sections Affected, 1949–1963, 1964–1972, 1973–1985, or 1986–2000, published in 11 separate volumes. For the period beginning January 1, 2001, a ''List of CFR Sections Affected'' is published at the end of each CFR volume.

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What is incorporation by reference? Incorporation by reference was established by statute and allows Federal agencies to meet the requirement to publish regulations in the Federal Register by referring to materials already published elsewhere. For an incorporation to be valid, the Director of the Federal Register must approve it. The legal effect of incorporation by reference is that the material is treated as if it were published in full in the Federal Register (5 U.S.C. 552(a)). This material, like any other properly issued regulation, has the force of law.

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(b) The matter incorporated is in fact available to the extent necessary to afford fairness and uniformity in the administrative process.

(c) The incorporating document is drafted and submitted for publication in accordance with 1 CFR part 51.

Properly approved incorporations by reference in this volume are listed in the Finding Aids at the end of this volume.

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A subject index to the Code of Federal Regulations is contained in a separate volume, revised annually as of January 1, entitled CFR INDEX AND FINDING AIDS. This volume contains the Parallel Table of Statutory Authorities and Agency Rules (Table I). A list of CFR titles, chapters, and parts and an alphabetical list of agencies publishing in the CFR are also included in this volume.

An index to the text of ''Title 3—The President'' is carried within that volume.

The Federal Register Index is issued monthly in cumulative form. This index is based on a consolidation of the ''Contents'' entries in the daily Federal Register.

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RAYMOND A. MOSLEY,
Director,
Office of the Federal Register.

October 1, 2005.

THIS TITLE

Title 42—PUBLIC HEALTH is composed of three volumes. The parts in these volumes are arranged in the following order: Parts 1–399, parts 400–429 and part 430 to end. The first volume (parts 1–399) contains current regulations issued under chapter I—Public Health Service (HHS). The second volume (parts 400–429) includes regulations issued under chapter IV—Centers for Medicare & Medicaid Services (HHS) and the third volume (part 430 to end) contains the remaining regulations in chapter IV and the regulations issued under chapter V by the Office of Inspector General-Health Care (HHS). The contents of these volumes represent all current regulations codified under this title of the CFR as of October 1, 2005.

The OMB control numbers for the Centers for Medicare & Medicaid Services appear in § 400.310 of chapter IV. For the convenience of the user subpart C consisting of §§ 400.300–400.310 is reprinted in the Finding Aids section of the third volume.

For this volume, Robert J. Sheehan was Chief Editor. The Code of Federal Regulations publication program is under the direction of Frances D. McDonald, assisted by Alomha S. Morris.

Title 42—Public Health

(This book contains parts 400 to 429)

Part

CHAPTER IV—Centers for Medicare & Medicaid Services, Department of Health and Human Services 400

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

EDITORIAL NOTE: Nomenclature changes to chapter IV appear at 62 FR 46037, Aug. 29, 1997; 66 FR 39452, July 31, 2001; and 67 FR 36540, May 24, 2002.

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SUBCHAPTER A—GENERAL PROVISIONS

PART 400—INTRODUCTION; DEFINITIONS

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400.200 General definitions.
400.202 Definitions specific to Medicare.
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Subpart C—OMB Control Numbers for Approved Collections of Information

400.300 Scope.
400.310 Display of currently valid OMB control numbers.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

Subpart A [Reserved]

Subpart B—Definitions

§ 400.200 General definitions.

In this chapter, unless the context indicates otherwise—

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).

ALJ stands for administrative law judge.

Area means the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

CMP stands for competitive medical plan.

Conditions of participation includes *requirements for participation* as the latter term is used in part 483 of this chapter.

Condition level deficiencies includes deficiencies with respect to ''level A requirements'' as the latter term is used in parts 442 and 483 of this chapter.

CORF stands for comprehensive outpatient rehabilitation facility.

CFR stands for Code of Federal Regulations.

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

CY stands for calendar year.

DAB stands for Departmental Appeals Board.

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

ESRD stands for end-stage renal disease.

FDA stands for the Food and Drug Administration.

FQHC means Federally qualified health center.

FR stands for FEDERAL REGISTER.

FY stands for fiscal year.

HCPP stands for health care prepayment plan.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

ICF/MR stands for intermediate care facility for the mentally retarded.

Medicaid means medical assistance provided under a State plan approved under title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under title XVIII of the Act.

NCD stands for national coverage determination.

OASDI stands for the Old Age, Survivors, and Disability Insurance program under title II of the Act.

OIG stands for the Department's Office of the Inspector General.

QDWI stands for Qualified Disabled and Working Individual.

QIO stands for quality improvement organization.

QMB stands for Qualified Medicare Beneficiary.

Qualified Disabled and Working Individual means an individual who—

(1) Is eligible to enroll for Medicare Part A under section 1818A of the Act.

(2) Has income, as determined in accordance with SSI methodologies, that does not exceed 200 percent of the Federal poverty guidelines (as defined and revised annually by the Office of Management and Budget) for a family of the size of the individual's family;

(3) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the relevant maximum amount established, for SSI eligibility, for an individual or for an individual and his or her spouse; and

(4) Is not otherwise eligible for Medicaid.

Qualified Medicare Beneficiary means an individual who—

(1) Is entitled to Medicare Part A, with or without payment of premiums, but is not entitled solely because he or she is eligible to enroll as a QDWI;

(2) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the maximum amount established for SSI eligibility; and

(3) Has income, as determined in accordance with SSI methodologies, that does not exceed 100 percent of the Federal poverty guidelines.

Quality improvement organization means an organization that has a contract with CMS, under part B of title XI of the Act, to perform utilization and quality control review of the health care furnished, or to be furnished, to Medicare beneficiaries.

Regional Administrator means a Regional Administrator of CMS.

Regional Office means one of the regional offices of CMS.

RHC stands for rural health clinic.

RRB stands for Railroad Retirement Board.

Secretary means the Secretary of Health and Human Services.

SNF stands for skilled nursing facility.

Social security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

SSA stands for Social Security Administration.

United States means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

[48 FR 12534, Mar. 25, 1983, as amended at 49 FR 7206, Feb. 27, 1984; 50 FR 15326 and 15358, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985; 51 FR 43197, Dec. 1, 1986; 52 FR 27764, July 23, 1987; 56 FR 8852, Mar. 1, 1991; 56 FR 38077, Aug. 12, 1991; 57 FR 24975, June 12, 1992; 57 FR 55912, Nov. 25, 1992; 63 FR 35065, June 26, 1998; 63 FR 52611, Oct. 1, 1998; 63 FR 68690, Dec. 14, 1998; 66 FR 39452, July 31, 2001; 67 FR 36540, May 24, 2002]

§ 400.202 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

Beneficiary means a person who is entitled to Medicare benefits.

Carrier means an entity that has a contract with CMS to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

Critical access hospital (CAH) means a facility designated by HFCA as meeting the applicable requirements of section 1820 of the Act and of subpart F of part 485 of this chapter.

Departmental Appeals Board means: (1) Except as provided in paragraphs (2) and (3) of this definition, a Board established in the office of the Secretary, whose members act in panels to provide impartial review of disputed decisions made by operating components of the Department or by ALJs.

(2) For purposes of review of ALJ decisions under part 405, subparts G and H; part 417, subpart Q; part 422, subpart M; and part 478, subpart B of this chapter, the Medicare Appeals Council designated by the Board Chair.

(3) For purposes of part 426 of this chapter, a Member of the Board and, at the discretion of the Board Chair, any other Board staff appointed by the Board Chair to perform a review under that part.

Entitled means that an individual meets all the requirements for Medicare benefits.

Essential access community hospital (EACH) means a hospital designated by CMS as meeting the applicable requirements of section 1820 of the Act and of subpart G of part 412 of this chapter, as in effect on September 30, 1997.

GME stands for graduate medical education.

Hospital insurance benefits means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of title XVIII of the Act.

Intermediary means an entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

Local coverage determination (LCD) means a decision by a fiscal intermediary or a carrier under Medicare Part A or Part B, as applicable, whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with section 1862(a)(1)(A) of the Act. An LCD may provide that a service is not reasonable and necessary for certain diagnoses and/or for certain diagnosis codes. An LCD does not include a determination of which procedure code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

Medicare Part A means the hospital insurance program authorized under Part A of title XVIII of the Act.

Medicare Part B means the supplementary medical insurance program authorized under Part B of title XVIII of the Act.

Medicare Part C means the choice of Medicare benefits through Medicare Advantage plans authorized under Part C of the title XVIII of the Act.

Medicare Part D means the voluntary prescription drug benefit program authorized under Part D of title XVIII of the Act.

National coverage determination (NCD) means a decision that CMS makes regarding whether to cover a particular service nationally under title XVIII of the Act. An NCD does not include a determination of what code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

Nonparticipating supplier means a supplier that does not have an agreement with CMS to participate in Part B of Medicare in effect on the date of the service.

Participating supplier means a supplier that has an agreement with CMS to participate in Part B of Medicare in effect on the date of the service.

Payment on an assignment-related basis means payment for Part B services—

(1) To a physician or other supplier that accepts assignment from the beneficiary, in accordance with § 424.55 or § 424.56 of this chapter;

(2) To a physician or other supplier after the beneficiary's death, in accordance with § 424.64(c)(1) of this chapter; or

(3) To an entity that pays the physician or other supplier under a health benefit plan, in accordance with § 424.66 of this chapter.

Provider means a hospital, a CAH, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Railroad retirement benefits means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, CAH, or SNF facilities.

Supplementary medical insurance benefits means payment to or on behalf of an entitled individual for services covered under Part B of title XVIII of the Act.

Supplier means a physician or other practitioner, or an entity other than a

provider, that furnishes health care services under Medicare.

[48 FR 12534, Mar. 25, 1983, as amended at 48 FR 56024, Dec. 16, 1983; 49 FR 3658, Jan. 30, 1984; 51 FR 43197, Dec. 1, 1986; 52 FR 27764, July 23, 1987; 55 FR 24567, June 18, 1990; 56 FR 8852, Mar. 1, 1991; 58 FR 30666, May 26, 1993; 59 FR 6576, Feb. 11, 1994; 60 FR 63175, Dec. 8, 1995; 62 FR 46025, Aug. 29, 1997; 62 FR 59098, Oct. 31, 1997; 63 FR 35065, June 26, 1998; 68 FR 63715, Nov. 11, 2003; 70 FR 4525, Jan. 28, 2005]

§ 400.203 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

Applicant means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

Federal financial participation (FFP) means the Federal Government's share of a State's expenditures under the Medicaid program.

FMAP stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

Medicaid agency or *agency* means the single State agency administering or supervising the administration of a State Medicaid plan.

Nursing facility (NF), effective October 1, 1990, means an SNF or an ICF participating in the Medicaid program.

PCCM stands for primary care case manager.

PCP stands for primary care physician.

Provider means either of the following:

(1) For the fee-for-service program, any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

(2) For the managed care program, any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

Recipient means an individual who has been determined eligible for Medicaid.

Services means the types of medical assistance specified in section 1905(a) of the Act and defined in subpart A of part 440 of this chapter.

State means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State plan or *the plan* means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administration of a Medicaid program in accordance with Federal requirements.

[48 FR 12534, Mar. 25, 1983, as amended at 50 FR 33029, Aug. 16, 1985; 56 FR 8852, Mar. 1, 1991; 57 FR 29155, June 30, 1992; 67 FR 41094, June 14, 2002]

Subpart C—OMB Control Numbers for Approved Collections of Information

SOURCE: 49 FR 4477, Feb. 7, 1984, unless otherwise noted.

§ 400.300 Scope.

This subpart collects and displays control numbers assigned by the Office of Management and Budget (OMB) to collections of information contained in CMS regulations, in accordance with OMB's regulations for controlling paperwork burdens on the public, 5 CFR part 1320. CMS intends that the subpart comply with the requirements of section 3507(f) of the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35 which requires that agencies shall not engage in a ''collection of information'' without obtaining a control number from OMB.

§ 400.310 Display of currently valid OMB control numbers.

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[60 FR 50445, Sept. 29, 1995, as amended at 60 FR 63188, Dec. 8, 1995]

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh). Subpart F is also issued under the authority of the Federal Claims Collection Act (31 U.S.C. 3711).

Subpart A [Reserved]

Subpart B—Confidentiality and Disclosure

SOURCE: 46 FR 55696, Nov. 12, 1981, unless otherwise noted.

§ 401.101 Purpose and scope.

(a) The regulations in this subpart:

(1) Implement section 1106(a) of the Social Security Act as it applies to the Centers for Medicare & Medicaid Services (CMS). The rules apply to information obtained by officers or employees of CMS in the course of administering title XVIII of the Social Security Act (Medicare), information obtained by Medicare intermediaries or carriers in the course of carrying out agreements under sections 1816 and 1842 of the Social Security Act, and any other information subject to section 1106(a) of the Social Security Act;

(2) Relate to the availability to the public, under 5 U.S.C. 552, of records of CMS and its components. They set out what records are available and how they may be obtained; and

(3) Supplement the regulations of the Department of Health and Human Services relating to availability of information under 5 U.S.C. 552, codified in 45 CFR part 5, and do not replace or restrict them.

(b) Except as authorized by the rules in this subpart, no information described in paragraph (a)(1) of this section shall be disclosed. The procedural rules in this subpart (§§ 401.106 through 401.152) shall be applied to requests for information which is subject to the rules for disclosure in this subpart.

(c) Requests for information which may not be disclosed according to the provisions of this subpart shall be denied under authority of section 1106(a) of the Social Security Act and this subpart, and furthermore, such requests which have been made pursuant to the Freedom of Information Act shall be denied under authority of an appropriate Freedom of Information Act exemption, 5 U.S.C. 552(b).

§ 401.102 Definitions.

For purposes of this subpart:

Act means the Social Security Act.

Freedom of Information Act rules means the substantive mandatory disclosure provisions of the Freedom of Information Act, 5 U.S.C. 552 (including the exemptions from mandatory disclosure, 5 U.S.C. 552(b), as implemented by the Department's public information regulation, 45 CFR part 5, subpart F and by §§ 401.106 to 401.152 of this subpart.

Person means a person as defined in the Administrative Procedure Act, 5 U.S.C. 551(2). This includes State or local agencies, but does not include

Federal agencies or State or Federal courts.

Record has the same meaning as that provided in 45 CFR 5.5.

Subject individual means an individual whose record is maintained by the Department in a system of records, as the terms ''individual,'' ''record'', and ''system of records'' are defined in the Privacy Act of 1974, 5 U.S.C. 552a(a).

§401.105 Rules for disclosure.

(a) *General rule*. The Freedom of Information Act rules shall be applied to every proposed disclosure of information. If, considering the circumstances of the disclosure, the information would be made available in accordance with the Freedom of Information Act rules, then the information may be disclosed regardless of whether the requester or recipient of the information has a statutory right to request the information under the Freedom of Information Act, 5 U.S.C. 552, or whether a request has been made.

(b) *Application of the general rule*. Pursuant to the general rule in paragraph (a) of this section,

(1) Information shall be disclosed—

(i) To a subject individual when required by the access provision of the Privacy Act, 5 U.S.C. 552a(d), as implemented by the Department Privacy Act regulation, 45 CFR part 5b; and

(ii) To a person upon request when required by the Freedom of Information Act, 5 U.S.C. 552;

(2) Unless prohibited by any other statute (e.g., the Privacy Act of 1974, 5 U.S.C. 552a(b), the Tax Reform Act of 1976, 26 U.S.C. 6103, or section 1106(d) and (e) of the Social Security Act), information may be disclosed to any requester or recipient of the information, including another Federal agency or a State or Federal court, when the information would not be exempt from mandatory disclosure under Freedom of Information Act rules or when the information nevertheless would be made available under the Department's public information regulation's criteria for disclosures which are in the public interest and consistent with obligations of confidentiality and administrative necessity, 45 CFR part 5, subpart F, as supplemented by §§401.106 to 401.152 of this subpart.

[42 FR 14704, Mar. 16, 1977. Redesignated at 45 FR 74913, 74914, Nov. 13, 1980, and correctly redesignated at 46 FR 24551, May 1, 1981, as amended at 46 FR 55697, Nov. 12, 1981]

§401.106 Publication.

(a) *Methods of publication*. Materials required to be published under the provisions of The Freedom of Information Act, 5 U.S.C. 552 (a)(1) and (2) are published in one of the following ways:

(1) By publication in the FEDERAL REGISTER of CMS regulations, and by their subsequent inclusion in the Code of Federal Regulations;

(2) By publication in the FEDERAL REGISTER of appropriate general notices;

(3) By other forms of publication, when incorporated by reference in the FEDERAL REGISTER with the approval of the Director of the Federal Register; and

(4) By publication of indexes of precedential orders and opinions issued in the adjudication of claims, statements of policy and interpretations which have been adopted but have not been published in the FEDERAL REGISTER, and of administrative staff manuals and instructions to staff that affect a member of the public.

(b) *Availability for inspection*. Those materials which are published in the FEDERAL REGISTER pursuant to 5 U.S.C. 552(a)(1) shall, to the extent practicable and to further assist the public, be made available for inspection at the places specified in §401.128.

[46 FR 55696, Nov. 12, 1981, as amended at 48 FR 22924, May 23, 1983]

§401.108 CMS rulings.

(a) After September 1981, a precedent final opinion or order or a statement of policy or interpretation that has not been published in the FEDERAL REGISTER as a part of a regulation or of a notice implementing regulations, but which has been adopted by CMS as having precedent, may be published in the FEDERAL REGISTER as a CMS Ruling and will be made available in the publication entitled *CMS Rulings*.

(b) Precedent final opinions and orders and statements of policy and interpretation that were adopted by CMS

before October, 1981, and that have not been published in the FEDERAL REGISTER are available in *CMS Rulings*.

(c) CMS Rulings are published under the authority of the Administrator, CMS. They are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

[48 FR 22924, May 23, 1983, as amended at 70 FR 11472, Mar. 8, 2005; 70 FR 37702, June 30, 2005]

§ 401.110 Publications for sale.

The following publications containing information pertaining to the program, organization, functions, and procedures of CMS may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402.

(a) Titles 20, 42, and 45 of the Code of Federal Regulations.

(b) FEDERAL REGISTER issues.

(c) Compilation of the Social Security Laws.

(d) CMS Rulings.

(e) Social Security Handbook. The information in the Handbook is not of precedent or interpretative force.

(f) Medicare/Medicaid Directory of Medical Facilities.

§ 401.112 Availability of administrative staff manuals.

All CMS administrative staff manuals and instructions to staff personnel which contain policies, procedures, or interpretations that affect the public are available for inspection and copying. A complete listing of such materials is published in CMS Rulings. These manuals are generally not printed in a sufficient quantity to permit sale or other general distribution to the public. Selected material is maintained at Social Security Administration district offices and field offices and may be inspected there. See §§ 401.130 and 401.132 for a listing of this material.

§ 401.116 Availability of records upon request.

(a) *General*. In addition to the records made available pursuant to §§ 401.106, 401.108, 401.110 and 401.112, CMS will, upon request made in accordance with this subpart, make identified records available to any person, unless they are exempt from disclosure under the provisions of section 552(b) of title 5, United States Code (see § 401.126), or any other provision of law.

(b) *Misappropriation, alteration, or destruction of records*. No person may remove any record made available to him for inspection or copying under this part, from the place where it is made available. In addition, no person may steal, alter, mutilate, obliterate, or destroy in whole or in part, such a record. See sections 641 and 2071 of title 18 of the United States Code.

§ 401.118 Deletion of identifying details.

When CMS publishes or otherwise makes available an opinion or order, statement of policy, or other record which relates to a private party or parties, the name or names or other identifying details will be deleted.

§ 401.120 Creation of records.

Records will not be created by compiling selected items from the files, and records will not be created to provide the requester with such data as ratios, proportions, percentages, per capitas, frequency distributions, trends, correlations, and comparisons. If such data have been compiled and are available in the form of a record, the record shall be made available as provided in this subpart.

§ 401.126 Information or records that are not available.

(a) *Specific exemptions from disclosure*. Pursuant to paragraph (b) of 5 U.S.C. 552, certain classes of records are exempt from disclosure. For some examples of the kinds of materials which are exempt, see subpart F of the public information regulation of the Department of Health and Human Services (45 CFR part 5) and the appendix to that regulation.

(b) *Materials exempt from disclosure by statute*. Pursuant to paragraph (b)(3) of

5 U.S.C. 552, as amended, which exempts from the requirement for disclosure matters that are exempted from disclosure by statute, provided that such statute requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or establishes particular criteria for withholding or refers to particular types of matter to be withheld:

(1) Reports described in sections 1106 (d) and (e) of the Social Security Act shall not be disclosed, except in accordance with the provisions of sections 1106 (d) and (e). Sections 1106 (d) and (e) provide for public inspection of certain official reports dealing with the operation of the health programs established by titles XVIII and XIX of the Social Security Act (Medicare and Medicaid), but require that program validation survey reports and other formal evaluations of providers of services shall not identify individual patients, individual health care practitioners, or other individuals. Section 1106(e) further requires that none of the reports shall be made public until the contractor or provider whose performance is being evaluated has had a reasonable opportunity to review that report and to offer comments. See §401.133 (b) and (c);

(2)(i) Except as specified in paragraph (b)(2)(ii) of this section, CMS may not disclose any accreditation survey or any information directly related to the survey (including corrective action plans) made by and released to it by the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association or any other national accreditation organization that meets the requirements of §488.6 or §493.506 of this chapter. Materials that are confidential include accreditation letters and accompanying recommendations and comments prepared by an accreditation organization concerning the entities it surveys.

(ii) *Exceptions*.

(A) CMS may release the accreditation survey of any home health agency; and

(B) CMS may release the accreditation survey and other information directly related to the survey (including corrective action plans) to the extent the survey and information relate to an enforcement action (for example, denial of payment for new admissions, civil money penalties, temporary management and termination) taken by CMS; and

(3) Tax returns and return information defined in section 6103 of the Internal Revenue Code, as amended by the Tax Reform Act of 1976, shall not be disclosed except as authorized by the Internal Revenue Code.

(c) *Effect of exemption*. Neither 5 U.S.C. 552 nor this regulation directs the withholding of any record or information, except to the extent of the prohibitions in paragraph (b) of this section. Except for material required to be withheld under the statutory provisions incorporated in paragraph (b) of this section or under another statute which meets the standards in 5 U.S.C. 552(b)(3), materials exempt from mandatory disclosure will nevertheless be made available when this can be done consistently with obligations of confidentiality and administrative necessity. The disclosure of materials or records under these circumstances in response to a specific request, however, is of no precedent force with respect to any other request.

[46 FR 55696, Nov. 12, 1981, as amended at 58 FR 61837, Nov. 23, 1993]

§401.128 Where requests for records may be made.

(a) *General*. Any request for any record may be made to—

(1) Any CMS component;

(2) Director, Office of Public Affairs, CMS 313–H, Hubert H. Humphrey Building, 200 Independence Avenue, Washington, DC 20201; or

(3) Director of Public Affairs in any Regional Office of the Department of Health and Human Services.

The locations and service areas of these offices are as follows:

Region I—John F. Kennedy Federal Building, Boston, MA 02203. Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.

Region II—26 Federal Plaza, New York, NY 10007. New York, New Jersey, Puerto Rico, Virgin Islands.

Region III—Gateway Building, 3535 Market Street, Philadelphia, PA 19101. Delaware, Maryland, Pennsylvania, Virginia, West Virginia, District of Columbia.

Region IV—101 Marietta Street, Atlanta, GA 30323. Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee.

Region V—300 South Wacker Drive, Chicago, IL 60606. Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin.

Region VI—1200 Main Tower Building, Dallas, TX 75202. Arkansas, Louisiana, New Mexico, Oklahoma, Texas.

Region VII—601 East 12th Street, Kansas City, MO 64106. Iowa, Kansas, Missouri, Nebraska.

Region VIII—Federal Office Building, 19th and Stout Streets, Denver, CO 80294. Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming.

Region IX—Federal Office Building, 50 United Nations Plaza, San Francisco, CA 94102. Arizona, California, Hawaii, Nevada, Guam, Trust Territory of Pacific Islands, American Samoa.

Region X—Arcade Plaza Building, 1321 Second Avenue, Seattle, WA 98101. Alaska, Idaho, Oregon, Washington.

(b) *Records pertaining to individuals.* CMS maintains some records pertaining to individuals. Disclosure of such records is generally prohibited by section 1106 of the Social Security Act (42 U.S.C. 1306), except as prescribed in § 401.105 (See also § 401.126(b)). Requests for records pertaining to individuals may be addressed to:

Director, Office of Research, Demonstrations and Statistics, CMS, Baltimore, Maryland 21235, when information is sought from the record of a person who has participated in a research survey conducted by or for CMS, Office of Research, Demonstrations and Statistics; or whose records have been included by statistical sampling techniques in research and statistical studies authorized by the Social Security Act in the field of health care financing.

(c) *Requests for materials listed in § 401.130 or § 401.132 or indexed in the CMS Rulings.* A request to inspect and copy materials listed in § 401.130 or § 401.132 or indexed in CMS Rulings may be made to any district or branch office of the Social Security Administration. If the specific material requested is not available in the office receiving the request, the material will be obtained and made available promptly.

§ 401.130 Materials available at social security district offices and branch offices.

(a) *Materials available for inspection.* The following are available or will be made available for inspection at the social security district offices and branch offices:

(1) Compilation of the Social Security Laws.

(2) The Public Information Regulation of the Department of Health and Human Services (45 CFR part 5).

(3) Medicare Program regulations issued by the Centers for Medicare & Medicaid Services. 42 CFR chapter IV .

(4) CMS Rulings.

(5) Social Security Handbook.

(b) *Materials available for inspection and copying.* The following materials are available or will be made available for inspection and copying at the social security district offices and branch offices:

(1) Claims Manual of the Social Security Administration.

(2) Department Staff Manual on Organization, Department of Health and Human Services, Part F, CMS.

(3) Parts 2 and 3 of the Part A

Intermediary Manual (Provider Services under Medicare CMS Pub. 13–2 and 13–3).

(4) Parts 2 and 3 of the Part B Intermediary Manual (Physician and Supplier Services).

(5) Intermediary Letters Related to Parts 2 and 3 of the Part A and Part B Intermediary Manuals.

(6) State Buy-In Handbook (State Enrollment of Eligible Individuals under the Supplementary Medical Insurance Program) and Letters.

(7) Group Practice Prepayment Plan Manual (HIM–8) and Letters.

(8) State Operations Manual (HIM–7).

(9) CMS Letters to State Agencies on Medicare.

(10) Skilled Nursing Facility Manual (CMS Pub. 12).

(11) Hearing Officers Handbook (Supplementary Medical Insurance Program—HIM–21).

(12) Hospital Manual (HIM–10).

(13) Home Health Agency Manual (HIM–11).

(14) Outpatient Physical Therapy Provider Manual (HIM–9).

(15) Provider Reimbursement Manual (HIM–15).

(16) Audit Program Manuals for Hospital (HIM–16), Home Health Agency (HIM–17), and Extended Care Facilities (HIM–18).

(17) Statements of deficiencies based upon survey reports of health care institutions or facilities prepared after January 31, 1973, by a State agency, and such reports (including pertinent written statements furnished by such institution or facility on such statements of deficiencies), as set forth in §401.133(a). Except as otherwise provided for at §§401.133 and 488.325 of this chapter for SNFs, such statements of deficiencies, reports, and pertinent written statements shall be available or made available only at the social security district office and regional office servicing the area in which the institution or facility is located, except that such statements of deficiencies and pertinent written statements shall also be available at the local public assistance offices servicing such area.

(18) Indexes to the materials listed in paragraph (a) of this section and in this paragraph (b) and an index to the Bureau of Hearings and Appeals Handbook.

[46 FR 55696, Nov. 12, 1981, as amended at 59 FR 56232, Nov. 10, 1994]

§401.132 Materials in field offices of the Office of Hearings and Appeals, SSA.

(a) *Materials available for inspection.* The following materials are available for inspection in the field offices of the Office of Hearings and Appeals, SSA.

(1) Title 45 of the Code of Federal Regulations (including the public information regulation of the Department of Health and Human Services).

(2) Regulations of the Social Security Administration and CMS.

(3) Title 5, United States Code.

(4) Compilation of the Social Security Laws.

(5) CMS Rulings.

(6) Social Security Handbook.

(b) *Handbook available for inspection and copying.* The Office of Hearings and Appeals Handbook is available for inspection and copying in the field offices of the Office of Hearings and Appeals.

§401.133 Availability of official reports on providers and suppliers of services, State agencies, intermediaries, and carriers under Medicare.

Except as otherwise provided for in §488.325 of this chapter for SNFs, the following must be made available to the public under the conditions specified:

(a) *Statements of deficiencies and survey reports on providers of services prepared by State agencies.* (1) Statements of deficiencies based upon official survey reports prepared after January 31, 1973, by a State agency pursuant to its agreement entered into under section 1864 of the Social Security Act and furnished to CMS, which relate to a State agency's findings on the compliance of a health care institution or facility with the applicable provisions in section 1861 of the Act and with the regulations, promulgated pursuant to those provisions, dealing with health and safety of patients in those institutions and facilities; and (2) State agency survey reports. The statement of deficiencies or report and any pertinent written statements furnished by the institution or facility on the statement of deficiencies shall be disclosed within 90 days following the completion of the survey by the State agency, but not to exceed 30 days following the receipt of the report by CMS. (See §401.130(b)(17)) for places where statements of deficiencies, reports, and pertinent written statements will be available.)

(b) *CMS reports on providers of services.* Upon request in writing, official reports and other formal evaluations (including followup reviews), excluding references to internal tolerance rules and practices contained therein, internal working papers or other informal memoranda, prepared and completed after January 31, 1973, which relate to the performance of providers of services under Medicare: *Provided,* That no information identifying individual patients, physicians, or other practitioners, or other individuals shall be disclosed under this paragraph. Those reports and other evaluations shall be disclosed within 30 days following the final preparation thereof by CMS during which time the providers of services shall be afforded a reasonable opportunity to offer comments, and there

shall be disclosed with those reports and evaluations any pertinent written statements furnished CMS by those providers on those reports and evaluations.

(c) *Contractor performance review reports.* Upon request in writing, official contractor performance review reports and other formal evaluations (including followup reviews), excluding references to internal tolerance rules and practices contained therein, internal working papers or other informal memoranda, prepared and completed after January 31, 1973, which relate to the evaluation of the performance of (1) intermediaries and carriers under their agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act and (2) State agencies under their agreements entered into pursuant to section 1864 of the Act (including comparative evaluations of the performance of those intermediaries, carriers, and State agencies). The latest Contract Performance Review Report pertaining to a particular intermediary or carrier, prepared prior to February 1, 1973, may also be disclosed to any person upon request in writing. Those reports and evaluations shall be disclosed within 30 days following their final preparation by CMS (or 30 days following the request therefor, in the case of the contract performance review report prepared prior to February 1, 1973), during which time those intermediaries, carriers, and State agencies, as the case may be, shall be afforded a reasonable opportunity to offer comments, and there shall be disclosed with those reports and evaluations any pertinent written statements furnished CMS by those intermediaries, carriers, on State agencies or those reports and evaluations.

(d) *Accreditation surveys.* Upon written request, CMS will release the accreditation survey and related information from an accreditation organization meeting the requirements of § 488.5, § 488.6 or § 493.506 of this chapter to the extent the survey and information relate to an enforcement action taken (for example, denial of payment for new admission, civil money penalties, temporary management and termination) by CMS;

(e) Upon written request, CMS will release the accreditation survey of any home health agency.

[46 FR 55696, Nov. 12, 1981; 46 FR 59249, Dec. 4, 1981, as amended at 58 FR 61838, Nov. 23, 1993; 59 FR 56232, Nov. 10, 1994]

§ 401.134 Release of Medicare information to State and Federal agencies.

(a) Except as provided in paragraph (b) of this section, the following information may be released to an officer or employee of an agency of the Federal or a State government lawfully charged with the administration of a program receiving grants-in-aid under title V and XIX of the Social Security Act for the purpose of administration of those titles, or to any officer or employee of the Department of Army, Department of Defense, solely for the administration of its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS):

(1) Information, including the identification number, concerning charges made by physicians, other practitioners, or suppliers, and amounts paid under Medicare for services furnished to beneficiaries by such physicians, other practioners, or suppliers, to enable the agency to determine the proper amount of benefits payable for medical services performed in accordance with those programs; or

(2) Information as to physicians or other practioners that has been disclosed under § 401.105.

(3) Information relating to the qualifications and certification status of hospitals and other health care facilities obtained in the process of determining whether, and certifying as to whether, institutions or agencies meet or continue to meet the conditions of participation of providers of services or whether other entities meet or continue to meet the conditions for coverage of services they furnish.

(b) The release of such information shall not be authorized by a fiscal intermediary or carrier.

(c) The following information may be released to any officer or employee of an agency of the Federal or a State government lawfully charged with the duty of conducting an investigation or prosecution with respect to possible

fraud or abuse against a program receiving grants-in-aid under Medicaid, but only for the purpose of conducting such an investigation or prosecution, or to any officer or employee of the Department of the Army, Department of Defense, solely for the administration of its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), provided that the agency has filed an agreement with CMS that the information will be released only to the agency's enforcement branch and that the agency will preserve the confidentiality of the information received and will not disclose that information for other than program purposes:

(1) The name and address of any provider of medical services, organization, or other person being actively investigated for possible fraud in connection with Medicare, and the nature of such suspected fraud. An active investigation exists when there is significant evidence supporting an initial complaint but there is need for further investigation.

(2) The name and address of any provider of medical services, organization, or other person found, after consultation with an appropriate professional association or a program review team, to have provided unnecessary services, or of any physician or other individual found to have violated the assignment agreement on at least three occasions.

(3) The name and address of any provider of medical services, organization or other person released under paragraph (c)(1) or (2) of this section concerning which an active investigation is concluded with a finding that there is no fraud or other prosecutable offense.

§401.135 Release of Medicare information to the public.

The following shall be made available to the public under the conditions specified:

(a) Information as to amounts paid to providers and other organizations and facilities for services to beneficiaries under title XVIII of the Act: *Provided*, That no information identifying any particular beneficiaries shall be disclosed under this paragraph.

(b) The name of any provider of services or other person furnishing services to Medicare beneficiaries who—

(1) Has been found by a Federal court to have been guilty of submitting false claims in connection with Medicare; or

(2) Has been found by a carrier or intermediary, after consultation with a professional medical association functioning external to program administration or, if appropriate, the State medical authority, to have been engaged in a pattern of furnishing services to beneficiaries which are substantially in excess of their medical needs; except that the name of any provider or other person shall not be disclosed pursuant to a finding under this paragraph (b)(2) of this section, unless that provider or other person has first been afforded a reasonable opportunity to offer evidence on his behalf.

(c) Upon request in writing, cost reports submitted by providers of services pursuant to section 1815 of the Act to enable the Secretary to determine amounts due the providers.

§401.136 Requests for information or records.

(a) A request should reasonably identify the requested record by brief description. Requesters who have detailed information which would assist in identifying the records requested are urged to provide such information in order to expedite the handling of the request. Envelopes in which written requests are submitted should be clearly identified as Freedom of Information requests. The request should include the fee or request determination of the fee. When necessary, a written request will be promptly forwarded to the proper office, and the requester will be advised of the date of the receipt and identification and address of the proper office.

(b) Determinations of whether records will be released or withheld will be made within 10 working days from date of receipt of the request in the office listed in §401.128 except where CMS extends this time and sends notice of such extension to the requester. Such extension may not exceed 10 additional working days and shall apply only where the following unusual circumstances exist:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the requests;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are requested in a single request; or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the request or among two or more components of CMS having a substantial interest in the subject matter of the request.

(c) If an extension is made, the requester will be notified in writing before the expiration of 10 working days from receipt of the request and will be given an explanation of why the extension was necessary and the date on which a determination will be made.

(d) Authority to extend the time limit with respect to any request for information or records is granted to the Director, Office of Public Affairs, CMS and to the Director of Public Affairs in any HHS Regional Office. Those officers and employees of CMS who are listed in § 401.144(a) as having authority to deny requests for information from records maintained on individuals are granted authority to extend the time limit for responding to requests for information from such records.

§ 401.140 Fees and charges.

(a) *Statement of policy*. It is CMS's policy to comply with certain requests for information services without charge. Except as otherwise determined pursuant to paragraph (c) of this section, fees will be charged for the following services with respect to all other requests for information from records which are reasonably identified by the requesters:

(1) Reproduction, duplication, or copying of records;

(2) Searches for records; and

(3) Certification or authentication of records.

(b) *Fee schedules*. The fee schedule is as follows:

(1) *Search for records*. Three dollars per hour: *Provided, however,* That no charge will be made for the first half hour.

(2) *Reproduction, duplication, or copying of records*. Ten cents per page where such reproduction can be made by commonly available photocopying machines. The cost of reproducing records which cannot be so photocopied will be determined on an individual basis at actual cost.

(3) *Certification or authentication of records*. Three dollars per certification or authentication.

(4) *Forwarding materials to destination*. Any special arrangements for forwarding which are requested shall be charged at actual cost; however, no charge will be made for postage.

(5) No charge will be made when the total amount does not exceed five dollars.

(c) *Waiver or reduction of fees*. Waiver or reduction of the fees in paragraph (b) of this section may be made upon a determination that such waiver or reduction is in the public interest because furnishing the information can be considered as primarily benefiting the general public. Such determination may be made by the appropriate officer or employee identified in § 401.144.

(d) *Sale of documents*. On occasion, a previously printed document may be available for sale to the public; the cost of supplying the document is one cent per page unless the document is available for sale from the Superintendent of Documents, in which case the price shall be that determined by the Superintendent.

§ 401.144 Denial of requests.

(a) *General authority*. Only the Director, Office of Public Affairs, CMS, and the Regional Directors of Public Affairs, HHS, are authorized to deny written requests to obtain, inspect or copy any CMS information or record.

(b) *Forms of denials*. (1) Oral requests may be dealt with orally, but the requester should be advised that the oral response is not an official determination and that an official determination may be obtained only by submitting the request in writing. Appropriate available assistance will be offered.

(2) Written Requests—Denials of written requests will be in writing and will contain the reasons for the denial

including, as appropriate, a statement that a document requested is nonexistent or not reasonably described or is subject to one or more clearly described exemption(s). Denials will also provide the requester with appropriate information on how to exercise the right of appeal.

§401.148 Administrative review.

(a) *Review by the Administrator*. A person whose request has been denied may initiate a review by filing a request for review with the Administrator of CMS, 700 East High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235, within 30 days of receipt of the determination to deny or within 30 days of receipt of records which are in partial response to his request if a portion of a request is granted and a portion denied, whichever is later. Upon receipt of a timely request for review, the Administrator will review the decision in question and the findings upon which it was based. Upon the basis of the data considered in connection with the decision and whatever other evidence and written argument is submitted by the person requesting the review or which is otherwise obtained, the Administrator or his designee will affirm or revise in whole or in part the findings and decision in question. A decision to affirm the denial will be made only upon concurrence of the Assistant Secretary for Public Affairs, or his designee, after consultation with the General Counsel or his or her designee, and the appropriate program policy official. Written notice of the decision of the Administrator will be mailed to the person who requested the review. A written decision will be made within 20 working days from receipt of the request for review. Extension of the time limit may be granted under the circumstances listed in §401.136(b) to the extent that the maximum 10 days limit on extensions has not been exhausted on the initial determination. The decision will include the basis for it and will advise the requester of his right to judicial review.

(b) *Failure of the Administrator to comply with the time limits*. Failure of the Administrator to comply with the time limits set forth in §401.136 and this section constitutes an exhaustion of the requester's administrative remedies.

§401.152 Court review.

Where the Administrator upon review affirms the denial of a request for records, in whole or in part, the requester may seek court review in the district court of the United States pursuant to 5 U.S.C. 552(a)(4)(B).

Subparts C–E [Reserved]

Subpart F—Claims Collection and Compromise

SOURCE: 48 FR 39064, Aug. 29, 1983, unless otherwise noted.

§401.601 Basis and scope.

(a) *Basis*. This subpart implements for CMS the Federal Claims Collection Act (FCCA) of 1966 (31 U.S.C. 3711), and conforms to the regulations (4 CFR parts 101–105) issued jointly by the General Accounting Office and the Department of Justice that generally prescribe claims collection standards and procedures under the FCCA for the Federal government.

(b) *Scope*. Except as provided in paragraphs (c) through (f) of this section, the regulations in this subpart describe CMS's procedures and standards for the collection of claims in any amount, and the compromise of, or the suspension or termination of collection action on, all claims for money or property that do not exceed $100,000 or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest, arising under any functions delegated to CMS by the Secretary.

(c) *Amount of claim*. CMS refers all claims that exceed $100,000 or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest, to the Department of Justice or the General Accounting Office for the compromise of claims, or the suspension or termination of collection action.

(d) *Related regulations*—(1) *Department regulations*. DHHS regulations applicable to CMS that generally implement

the FCCA for the Department are located at 45 CFR part 30. These regulations apply only to the extent CMS regulations do not address a situation.

(2) *CMS regulations.* The following regulations govern specific debt management situations encountered by CMS and supplement this subpart:

(i) Claims against Medicare beneficiaries for the recovery of overpayments are covered in 20 CFR 404.515.

(ii) Adjustments in Railroad Retirement or Social Security benefits to recover Medicare overpayments to individuals are covered in §§ 405.350—405.358 of this chapter.

(iii) Claims against providers, physicians, or other suppliers of services for overpayments under Medicare and for assessment of interest are covered in §§ 405.377 and 405.378 of this chapter, respectively.

(iv) Claims against beneficiaries for unpaid hospital insurance or supplementary medical insurance premiums under Medicare are covered in § 408.110 of this chapter.

(v) State repayment of Medicaid funds by installments is covered in § 430.48 of this chapter.

(e) *Collection and compromise under other statutes and at common law.* The regulations in this subpart do not—

(1) Preclude disposition by CMS of claims under statutes, other than the FCCA, that provide for the collection or compromise of a claim, or suspension or termination of collection action.

(2) Affect any rights that CMS may have under common law as a creditor.

(f) *Fraud.* The regulations in this subpart do not apply to claims in which there is an indication of fraud, the presentation of a false claim, or misrepresentation on the part of a debtor or any other party having an interest in the claim. CMS forwards these claims to the Department of Justice for disposition under 4 CFR 105.1.

(g) *Enforced collection.* CMS refers claims to the Department of Justice for enforced collection through litigation in those cases which cannot be compromised or on which collection action cannot be suspended or terminated in accordance with this subpart or the regulations issued jointly by the Attorney General and the Comptroller General.

[48 FR 39064, Aug. 29, 1983, as amended at 52 FR 48123, Dec. 18, 1987; 57 FR 56998, Dec. 2, 1992; 61 FR 49271, Sept. 19, 1996; 61 FR 63748, Dec. 2, 1996]

§ 401.603 Definitions.

For purposes of this subpart—

Claim means any debt owed to CMS.

Debtor means any individual, partnership, corporation, estate, trust or other legal entity against which CMS has a claim.

§ 401.605 Omissions not a defense.

The failure of CMS to comply with the regulations in this subpart, or with the related regulations listed in § 401.601(d), is not available as a defense to a debtor against whom CMS has a claim for money or property.

§ 401.607 Claims collection.

(a) *General policy.* CMS recovers amounts of claims due from debtors, including interest where appropriate, by—

(1) Direct collections in lump sums or in installments; or

(2) Offsets against monies owed to the debtor by the Federal government where possible.

(b) *Collection in lump sums.* Whenever possible, CMS attempts to collect claims in full in one lump sum. However, if CMS determines that a debtor is unable to pay the claim in one lump sum, CMS may instead enter into an agreement to accept regular installment payments.

(c) *Collection in installments.* Generally, CMS requires that all claims to be satisfied by installment payments must be liquidated in three years or less. If unusual circumstances exist, such as the possibility of debtor insolvency, an installment agreement that extends beyond three years may be approved.

(1) *Debtor request.* If a debtor desires to repay a claim in installments, the debtor must submit—

(i) A request to CMS; and

(ii) Any information required by CMS to make a decision regarding the request.

(2) *CMS decision.* CMS will determine the number, amount and frequency of

installment payments based on the information submitted by the debtor and on other factors such as—

(i) Total amount of the claim;

(ii) Debtor's ability to pay; and

(iii) Cost to CMS of administering an installment agreement.

(d) *Collection by offset.* (1) CMS may offset, where possible, the amount of a claim against the amount of pay, compensation, benefits or other monies that a debtor is receiving or is due from the Federal government.

(2) Under regulations at §405.350—405.358 of this chapter, CMS may initiate adjustments in program payments to which an individual is entitled under title II of the Act (Federal Old Age, Survivors, and Disability Insurance Benefits) or under the Railroad Retirement Act of 1974 (45 U.S.C. 231) to recover Medicare overpayments.

[48 FR 39064, Aug. 29, 1983, as amended at 61 FR 49271, Sept. 19, 1996; 61 FR 63748, Dec. 2, 1996]

§401.613 Compromise of claims.

(a) *Amount of compromise.* HFCA requires that the amount to be recovered through a compromise of a claim must—

(1) Bear a reasonable relation to the amount of the claim; and

(2) Be recoverable through enforced collection procedures.

(b) *General factors.* After considering the bases for a decision to compromise a claim under paragraph (c) of this section, CMS may further consider factors such as—

(1) The age and health of the debtor if the debtor is an individual;

(2) Present and potential income of the debtor; and

(3) Whether assets have been concealed or improperly transferred by the debtor.

(c) *Basis for compromise.* Bases on which CMS may compromise a claim include the following—

(1) *Inability to pay.* CMS may compromise a claim if it determines that the debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount of the claim within a reasonable time.

(2) *Litigative probabilities.* CMS may compromise a claim if it determines that it would be difficult to prevail in a case before a court of law as a result of the legal issues involved or inability of the parties to agree to the facts of the case. The amount that CMS accepts in compromise under this provision will reflect—

(i) The likelihood that CMS would have prevailed on the legal question(s) involved;

(ii) Whether and to what extent CMS would have obtained a full or partial recovery of a judgment, depending on the availability of witnesses, or other evidentiary support for CMS's claim; and

(iii) The amount of court costs that would be assessed to CMS.

(3) *Cost of collecting the claim.* CMS may compromise a claim if it determines that the cost of collecting the claim does not justify the enforced collection of the full amount. In this case, CMS may adjust the amount it accepts as a compromise to allow an appropriate discount for the costs of collection it would have incurred but for the compromise.

(d) *Enforcement policy.* CMS may compromise statutory penalties, forfeitures, or debts established as an aid to enforcement or to compel compliance, if it determines that its enforcement policy, in terms of deterrence and securing compliance both present and future, is adequately served by acceptance of the compromise amount.

§401.615 Payment of compromise amount.

(a) *Time and manner of compromise.* Payment by the debtor of the amount that CMS has agreed to accept as a compromise in full settlement of a claim must be made within the time and in the manner prescribed by CMS. Accordingly, CMS will not settle a claim until the full payment of the compromise amount has been made.

(b) *Effect of failure to pay compromise amount.* Failure of the debtor to make payment, as provided by the compromise agreement, reinstates the full amount of the claim, less any amounts paid prior to the default.

(c) *Prohibition against grace periods.* CMS will not agree to inclusion of a provision in an installment agreement that would permit grace periods for

payments that are late under the terms of the agreement.

§ 401.617 Suspension of collection action.

(a) *General conditions.* CMS may temporarily suspend collection action on a claim if the following general conditions are met—

(1) *Amount of future recovery.* CMS determines that future collection action may result in a recovery of an amount sufficient to justify periodic review and action on the claim by CMS during the period of suspension.

(2) *Statute of limitations.* CMS determines that—

(i) The applicable statute of limitations has been tolled, waived or has started running anew; or

(ii) Future collections may be made by CMS through offset despite an applicable statute of limitations.

(b) *Basis for suspension.* Bases on which CMS may suspend collection action on a particular claim include the following—

(1) A debtor cannot be located; or

(2) A debtor—

(i) Owns no substantial equity in property;

(ii) Is unable to make payment on CMS's claim or is unable to effect a compromise; and

(iii) Has future prospects that justify retention of the claim.

(c) *Locating debtors.* CMS will make every reasonable effort to locate missing debtors sufficiently in advance of the bar of an applicable statute of limitations to permit timely filing of a lawsuit to recover the amount of the claim.

(d) *Effect of suspension on liquidation of security.* CMS will liquidate security, obtained in partial recovery of a claim, despite a decision under this section to suspend collection action against the debtor for the remainder of the claim.

§ 401.621 Termination of collection action.

(a) *General factors.* After considering the bases for a decision to terminate collection action under paragraph (b) of this section, CMS may further consider factors such as—

(1) The age and health of the debtor if the debtor is an individual;

(2) Present and potential income of the debtor; and

(3) Whether assets have been concealed or improperly transferred by the debtor.

(b) *Basis for termination of collection action.* Bases on which CMS may terminate collection action on a claim include the following—

(1) *Inability to collect a substantial amount of the claim.* CMS may terminate collection action if it determines that it is unable to collect, or to enforce collection, of a significant amount of the claim. In making this determination, CMS will consider factors such as—

(i) Judicial remedies available;

(ii) The debtor's future financial prospects; and

(iii) Exemptions available to the debtor under State or Federal law.

(2) *Inability to locate debtor.* In cases involving missing debtors, CMS may terminate collection action if—

(i) There is no security remaining to be liquidated;

(ii) The applicable statute of limitations has run; or

(iii) The prospects of collecting by offset, whether or not an applicable statute of limitations has run, are considered by CMS to be too remote to justify retention of the claim.

(3) *Cost of collection exceeds recovery.* CMS may terminate collection action if it determines that the cost of further collection action will exceed the amount recoverable.

(4) *Legal insufficiency.* CMS may terminate collection action if it determines that the claim is legally without merit.

(5) *Evidence unavailable.* CMS may terminate collection action if—

(i) Efforts to obtain voluntary payment are unsuccessful; and

(ii) Evidence or witnesses necessary to prove the claim are unavailable.

§ 401.623 Joint and several liability.

(a) *Collection action.* CMS will liquidate claims as quickly as possible. In cases of joint and several liability among two or more debtors, CMS will not allocate the burden of claims payment among the debtors. CMS will proceed with collection action against one

debtor even if other liable debtors have not paid their proportionate shares.

(b) *Compromise*. Compromise with one debtor does not release a claim against remaining debtors. Furthermore, CMS will not consider the amount of a compromise with one debtor to be a binding precedent concerning the amounts due from other debtors who are jointly and severally liable on the claim.

§ 401.625 Effect of CMS claims collection decisions on appeals.

Any action taken under this subpart regarding the compromise of a claim, or suspension or termination of collection action on a claim, is not an initial determination for purposes of CMS appeal procedures.

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

Subpart A—General Provisions

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Subpart B—Civil Money Penalties and Assessments

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Subpart C—Exclusions [Reserved]

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 63 FR 68690, Dec. 14, 1998, unless otherwise noted.

Subpart A—General Provisions

§ 402.1 Basis and scope.

(a) *Basis*. This part is based on the sections of the Act that are specified in paragraph (c) of this section.

(b) *Scope*. This part—

(1) Provides for the imposition of civil money penalties, assessments, and exclusions against persons that violate the provisions of the Act specified in paragraph (c), (d), or (e) of this section; and

(2) Sets forth the appeal rights of persons subject to penalties, assessments, or exclusion and the procedures for reinstatement following exclusion.

(c) *Civil money penalties*. CMS or OIG may impose civil money penalties against any person or other entity specified in paragraphs (c)(1) through (c)(33) of this section under the identified section of the Act. (The authorities that also permit imposition of an assessment or exclusion are noted in the applicable paragraphs.)

(1) Sections 1833(h)(5)(D) and 1842(j)(2)—Any person that knowingly and willfully, and on a repeated basis, bills for a clinical diagnostic laboratory test, other than on an assignment-related basis. This provision includes tests performed in a physician's office but excludes tests performed in a rural health clinic. (This violation may also include an assessment and cause exclusion.)

(2) Section 1833(i)(6)—Any person that knowingly and willfully presents, or causes to be presented, a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.

(3) Section 1833(q)(2)(B)—Any entity that knowingly and willfully fails to provide information about a referring physician, including the physician's name and unique physician identification number for the referring physician, when seeking payment on an unassigned basis. (This violation, if it occurs in repeated cases, may also cause an exclusion.)

(4) Sections 1834(a)(11)(A) and 1842(j)(2)—Any durable medical equipment supplier that knowingly and willfully charges for a covered service that

is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A). (This violation may also include an assessment and cause exclusion.)

(5) Sections 1834(a)(18)(B) and 1842(j)(2)—Any nonparticipating durable medical equipment supplier that knowingly and willfully, in violation of section 1834(a)(18)(A), fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (This violation may also include an assessment and cause exclusion.)

(6) Sections 1834(b)(5)(C) and 1842(j)(2)—Any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services. (This violation may also include an assessment and cause exclusion.)

(7) Sections 1834(c)(4)(C) and 1842(j)(2)—Any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(4)(B), for mammography screening. (This violation may also include an assessment and cause exclusion.)

(8) Sections 1834(h)(3) and 1842(j)(2)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing). (This violation may also include an assessment and cause exclusion.)

(9) Section 1834(j)(2)(A)(iii)—Any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully distributes a certificate of medical necessity in violation of section 1834(j)(2)(A)(i) or fails to provide the information required under section 1834(j)(2)(A)(ii).

(10) Sections 1834(j)(4) and 1842(j)(2)—

(i) Any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance under section 1834(a)(15); or

(C) The service is determined not to be medically necessary or reasonable.

(ii) These violations may also include an assessment and cause exclusion.

(11) Sections 1842(b)(18)(B) and 1842(j)(2)—Any practitioner specified in section 1842(b)(18)(C) (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, and clinical psychologists) or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(12) Sections 1842(k) and 1842(j)(2)—Any physician who knowingly and willfully presents, or causes to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15). (This violation may also include an assessment and cause exclusion.)

(13) Sections 1842(l)(3) and 1842(j)(2)—Any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A). (This violation may also include an assessment and cause exclusion.)

(14) Sections 1842(m)(3) and 1842(j)(2)—(i) Any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least $500, who knowingly and willfully fails to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program.

(ii) This violation may also include an assessment and cause exclusion.

(15) Sections 1842(n)(3) and 1842(j)(2)—Any physician who knowingly and willfully, in repeated cases, bills one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B). (This violation may also include an assessment and cause exclusion.)

(16) Section 1842(p)(3)(A)—Any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis code or codes upon request by CMS or a carrier on any request for payment or bill not submitted on an assignment-related basis for any service furnished by the physician. (This violation, if it occurs in repeated cases, may also cause exclusion.)

(17) Sections 1848(g)(1)(B) and 1842(j)(2)—

(i) Any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis, that—

(A) Knowingly and willfully bills or collects in excess of the limiting charge (as defined in section 1848(g)(2)) on a repeated basis; or

(B) Fails to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv).

(ii) These violations may also include an assessment and cause exclusion.

(18) Section 1848(g)(3)(B) and 1842(j)(2)—Any person that knowingly and willfully bills for State plan approved physicians' services, as defined in section 1848(j)(3), on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (these individuals include qualified Medicare beneficiaries). This provision applies to services furnished on or after April 1, 1990. (This violation may also include an assessment and cause exclusion.)

(19) Section 1848(g)(4)(B)(ii), 1842(p)(3), and 1842(j)(2)(A)—

(i) Any physician, supplier, or other person (except any person that has been excluded from the Medicare program) that, for services furnished after September 1, 1990, knowingly and willfully—

(A) Fails to submit a claim on a standard claim form for services provided for which payment is made under Part B on a reasonable charge or fee schedule basis; or

(B) Imposes a charge for completing and submitting the standard claims form.

(ii) These violations, if they occur in repeated cases, may also cause exclusion.

(20) Section 1862(b)(5)(C)—Any employer (other than a Federal or other governmental agency) that, before October 1, 1998, willfully or repeatedly fails to provide timely and accurate information requested relating to an employee's group health insurance coverage.

(21) Section 1862(b)(6)(B)—Any entity that knowingly, willfully, and repeatedly—

(i) Fails to complete a claim form relating to the availability of other health benefit plans in accordance with section 1862(b)(6)(A); or

(ii) Provides inaccurate information relating to the availability of other health benefit plans on the claim form.

(22) Section 1877(g)(5)—Any person that fails to report information required by HHS under section 1877(f) concerning ownership, investment, and compensation arrangements. (This violation may also include an assessment and cause exclusion.)

(23) Sections 1879(h), 1834(a)(18), and 1842(j)(2)—

(i) Any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance under section 1834(a)(15) of the Act; or

(C) The service is determined not to be payable under section 1834(a)(17)(b) because of unsolicited telephone contacts.

(ii) These violations may also include an assessment and cause exclusion.

(24) Section 1882(a)(2)—Any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C). (This violation may also include an assessment and cause exclusion.)

(25) Section 1882(p)(8)—Any person that sells or issues Medicare supplemental policies, on or after July 30, 1992, that fail to conform to the NAIC or Federal standards established under section 1882(p). (This violation may also include an assessment and cause exclusion.)

(26) Section 1882(p)(9)(C)—

(i) Any person that sells a Medicare supplemental policy and—

(A) Fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits; or

(B) Fails to provide the individual, before the sale of the policy, an outline of coverage describing the benefits provided by the policy.

(ii) These violations may also include an assessment and cause exclusion.

(27) Section 1882(q)(5)(C)—

(i) Any person that fails to—

(A) Suspend a Medicare supplemental policy at the policyholder's request, if the policyholder applies for and is determined eligible for medical assistance, and the policyholder provides notice within 90 days of the eligibility determination; or

(B) Automatically reinstate the policy as of the date of termination of medical assistance if the policyholder loses eligibility for medical assistance and the policyholder provides notice within 90 days of loss of eligibility.

(ii) These violations may also include an assessment and cause exclusion.

(28) Section 1882(r)(6)(A)—Any person that fails to provide refunds or credits as required by section 1882(r)(1)(B). (This violation may also include an assessment and cause exclusion.)

(29) Section 1882(s)(4)—

(i) Any issuer of a Medicare supplemental policy that—

(A) Does not waive any time periods applicable to preexisting conditions, waiting periods, elimination periods, or probationary periods if the time periods were already satisfied under a preceding Medicare supplemental policy; or

(B) Denies a policy, conditions the issuance or effectiveness of the policy, or discriminates in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A).

(ii) These violations may also include an assessment and cause exclusion.

(30) Section 1882(t)(2)—

(i) Any issuer of a Medicare supplemental policy that—

(A) Fails substantially to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

(B) Imposes premiums on enrollees in excess of the premiums approved by the State;

(C) Acts to expel an enrollee for reasons other than nonpayment of premiums; or

(D) Does not provide each enrollee at the time of enrollment with the specific information provided in section 1882(t)(1)(E)(i) or fails to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii)).

(ii) These violations may also include an assessment and cause exclusion.

(31) Sections 1834(k)(6) and 1842(j)(2)—Any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(32) Sections 1834(l)(6) and 1842(j)(2)—Any supplier of ambulance services who knowingly and willfully bills or collects for any services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(33) Section 1806(b)(2)(B)—Any person who knowingly and willfully fails to furnish a beneficiary with an itemized

statement of items or services within 30 days of the beneficiary's request.

(d) *Assessments.* CMS or OIG may impose assessments in addition to civil money penalties for violations of the following statutory sections:

(1) Section 1833: Paragraph (h)(5)(D).

(2) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

(3) Section 1842: Paragraphs (k), (l)(3), (m)(3), and (n)(3).

(4) Section 1848: Paragraph (g)(1)(B).

(5) Section 1877: Paragraph (g)(5).

(6) Section 1879: Paragraph (h).

(7) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(3), and (t)(2).

(e) *Exclusions.* (1) CMS or OIG may exclude any person from participation in the Medicare program on the basis of any of the following violations of the statute:

(i) Section 1833: Paragraphs (h)(5)(D) and, in repeated cases, (q)(2)(B).

(ii) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

(iii) Section 1842: Paragraphs (b)(18)(B), (k), (l)(3), (m)(3), (n)(3), and, in repeated cases, (p)(3)(B).

(iv) Section 1848: Paragraphs (g)(1)(B), (g)(3)(B), and, in repeated cases, (g)(4)(B)(ii).

(v) Section 1877: Paragraph (g)(5).

(vi) Section 1879: Paragraph (h).

(vii) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(4), and (t)(2).

(2) CMS or OIG must exclude from participation in the Medicare program any of the following, under the identified section of the Act:

(i) Section 1834(a)(17)(C)—Any supplier of durable medical equipment and supplies that are covered under section 1834(a)(13) that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of covered services in violation of section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts as described under section 1834(a)(17)(A).

(ii) Section 1834(h)(3)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of prosthetic devices, orthotics, or prosthetics in the same manner as in the violation under section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts in the same manner as described in section 1834(a)(17)(C).

(f) *Responsible persons.* (1) If CMS or OIG determines that more than one person is responsible for any of the violations described in paragraph (c) or paragraph (d) of this section, it may impose a civil money penalty or a civil money penalty and assessment against any one of those persons or jointly and severally against two or more of those persons. However, the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person were responsible.

(2) A principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

(g) *Time limits.* Neither CMS nor OIG initiates an action to impose a civil money penalty, assessment, or proceeding to exclude a person from participation in the Medicare program unless it begins the action within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001]

§ 402.3 Definitions.

For purposes of this part:

Assessment means the amount described in § 402.107 and includes the plural of that term.

Assignment-related basis means that the claim submitted by a physician, supplier or other person is paid on the basis of an assignment, whereby the physician, supplier or other person agrees to accept the Medicare payment as payment in full for the services furnished to the beneficiary and is precluded from charging the beneficiary more than the deductible and coinsurance based upon the approved Medicare fee amount. Additional obligations, including obligations to make refunds in certain circumstances, are established at section 1842(b)(3) of the Act.

Claim means an application for payment for a service for which the Medicare or Medicaid program may pay.

Covered means that a service is described as reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. A service is not covered if it is specifically identified as excluded from Medicare Part B coverage or is not a defined Medicare Part B benefit.

Exclusion means the temporary or permanent barring of a person or other entity from participation in the Medicare or State health care program and that services furnished or ordered by that person are not paid for under either program.

General Counsel means the General Counsel of HHS or his or her designees.

Knowingly or *knowingly and willfully* means that a person, with respect to information—

(1) Has actual knowledge of the information;

(2) Acts in deliberate ignorance of the truth or falsity of the information; or

(3) Acts in reckless disregard of the truth or falsity of the information; and

(4) No proof of specific intent is required.

Medicare supplemental policy means a policy guaranteeing that a health plan will pay a policyholder's coinsurance and deductible and will cover other limitations on payment imposed under title XVIII of the Act and will provide additional health plan or non-Medicare coverage for services up to a predefined benefit limit.

NAIC stands for the National Association of Insurance Commissioners.

Nonparticipating describes a physician, supplier, or other person (excluding any provider of services) that, at the time of furnishing the services to Medicare Part B beneficiaries, is not a participating physician or supplier.

Participating describes a physician or supplier (excluding any provider of services) that, before the beginning of any given year, enters into an agreement with HHS that provides that the physician or supplier will accept payment under the Medicare program on an assignment-related basis for all services furnished to Medicare Part B beneficiaries.

Penalty means the amount described in § 402.105 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physicians' services means the following Medicare covered professional services:

(1) Surgery, consultation, home, office and institutional calls, and other professional services performed by physicians.

(2) Services and supplies furnished ''incident to'' a physician's professional services.

(3) Outpatient physical and occupational therapy services.

(4) Diagnostic x-ray tests and other diagnostic tests (excluding clinical diagnostic laboratory tests).

(5) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.

(6) Antigens prepared by a physician.

Radiologist service means radiology services performed only by, or under the direction of, a physician who is certified, or eligible to be certified, by the American Board of Radiology or for whom radiology services account for at least 50 percent of the total amount of charges made under part B of title XVIII of the Act.

Request for payment means an application submitted by a person to any person for payment for a service.

Respondent means the person upon which CMS or OIG has imposed, or proposes to impose, a civil money penalty, assessment, or exclusion.

Service includes—

(1) Any item, device, medical supply, or service claimed to have been furnished to a patient and listed in an itemized claim for program payment; or

(2) In the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Timely basis means that the adjustment to a bill or a refund is considered ''on a timely basis'' if the physician, supplier, or other person makes the adjustment or refund to the appropriate

party no later than 30 days after the date the physician, supplier, or other person is notified by the Medicare Part B contractor of the violation and the requirement to refund any excess collections.

§ 402.5 Right to a hearing before the final determination.

CMS or OIG does not make a determination adverse to any person under this part until the person has been given a written notice and opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

§ 402.7 Notice of proposed determination.

(a) If CMS or OIG proposes a penalty and, as applicable, an assessment, or proposes to exclude a respondent from participation in Medicare in accordance with this part, it sends the respondent written notice of its intent by certified mail, return receipt requested. The notice includes the following information:

(1) Reference to the statutory basis or bases for the penalty, assessment, exclusion, or any combination, as applicable.

(2)(i) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment, and exclusion are proposed; or

(ii) If CMS or OIG is relying upon statistical sampling to project the number and types of claims or requests for payment and the dollar amount, a description of the claims and requests for payment comprising the sample and a brief description of the statistical sampling technique CMS or OIG used.

(3) The reason why the claims, requests for payment, or incidents are subject to a penalty and assessment.

(4) The amount of the proposed penalty and of any proposed assessment.

(5) Any mitigating or aggravating circumstances that CMS or OIG considered when it determined the amount of the proposed penalty and any applicable assessment.

(6) Information concerning response to the notice, including—

(i) A specific statement of the respondent's right to a hearing; and

(ii) A statement that failure to request a hearing within 60 days renders the proposed determination final and permits the imposition of the proposed penalty and any assessment.

(iii) A statement that the debt may be collected through an administrative offset.

(7) In the case of a respondent that has an agreement under section 1866 of the Act, notice that imposition of an exclusion may result in termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

§ 402.9 Failure to request a hearing.

(a) If the respondent does not request a hearing within 60 days of receipt of the notice of proposed determination specified in § 402.7, any civil money penalty, assessment, or exclusion becomes final and CMS or OIG may impose the proposed penalty, assessment, or exclusion, or any less severe penalty, assessment, or suspension.

(b) CMS or OIG notifies the respondent by certified mail, return receipt requested, of any penalty, assessment, or exclusion that has been imposed and of the means by which the respondent may satisfy the judgment.

(c) The respondent has no right to appeal a penalty, assessment, or exclusion for which he or she has not requested a hearing.

§ 402.11 Notice to other agencies and other entities.

(a) Whenever a penalty, assessment, or exclusion becomes final, CMS or OIG notifies the following organizations and entities about the action and the reasons for it:

(1) The appropriate State or local medical or professional association.

(2) The appropriate quality improvement organization.

(3) As appropriate, the State agency responsible for the administration of each State health care program (Medicaid, the Maternal and Child Health Services Block Grant Program, and the Social Services Block Grant Program).

(4) The appropriate Medicare carrier or fiscal intermediary.

(5) The appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies).

(6) The long-term care ombudsman.

(b) For exclusions, CMS or OIG also notifies the public and specifies the effective date.

§ 402.13 Penalty, assessment, and exclusion not exclusive.

Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties prescribed by law.

§ 402.15 Collateral estoppel.

(a) When a final determination that the respondent presented or caused to be presented a claim or request for payment falling within the scope of § 402.1 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent is bound by that determination in any proceeding under this part.

(b) A person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements is barred from denying the essential elements of the criminal offense if the proceedings under this part involve the same transactions.

§ 402.17 Settlement.

CMS or OIG has exclusive authority to settle any issues or case, without the consent of the ALJ or the Secretary, at any time before a final decision by the Secretary. Thereafter, the General Counsel has the exclusive authority.

§ 402.19 Hearings and appeals.

The hearings and appeals procedures set forth in part 1005 of chapter V of this title are available to any person that receives an adverse determination under this part. For an appeal of a civil money penalty, assessment, or exclusion imposed under this part, either CMS or OIG may represent the government in the hearing and appeals process.

§ 402.21 Judicial review.

After exhausting all available administrative remedies, a respondent may seek judicial review of a penalty, assessment, or exclusion that has become final. The respondent may seek review only with respect to a penalty, assessment, or exclusion with respect to which the respondent filed an exception under § 1005.21(c) of this title unless the court excuses the failure or neglect to urge the exception in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

Subpart B—Civil Money Penalties and Assessments

§ 402.105 Amount of penalty.

(a) *$2,000*. Except as provided in paragraphs (b) through (g) of this section, CMS or OIG may impose a penalty of not more than $2,000 for each service, bill, or refusal to issue a timely refund that is subject to a determination under this part and for each incident involving the knowing, willful, and repeated failure of an entity furnishing a service to submit a properly completed claim form or to include on the claim form accurate information regarding the availability of other health insurance benefit plans (§ 402.1(c)(21)).

(b) *$1,000*. CMS or OIG may impose a penalty of not more than $1,000 for the following:

(1) Per certificate of medical necessity knowingly and willfully distributed to physicians on or after December 31, 1994 that—

(i) Contains information concerning the medical condition of the patient; or

(ii) Fails to include cost information.

(2) Per individual about whom information is requested, for willful or repeated failure of an employer to respond to an intermediary or carrier about coverage of an employee or spouse under the employer's group health plan (§ 402.1(c)(20)).

(c) *$5,000*. CMS or OIG may impose a penalty of not more than $5,000 for each violation resulting from the following:

(1) The failure of a Medicare supplemental policy issuer, on a replacement

policy, to waive any time periods applicable to pre-existing conditions, waiting periods, elimination periods, or probationary periods that were satisfied under a preceding policy (§ 402.1(c)(29)); and

(2) Any issuer of any Medicare supplemental policy denying a policy, conditioning the issuance or effectiveness of the policy, or discriminating in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A). (§ 402.1(c)(29)).

(d) *$10,000*. (1) CMS or OIG may impose a penalty of not more than $10,000 for each day that reporting entity ownership arrangements is late (§ 402.1(c)(22)).

(2) CMS or OIG may impose a penalty of not more than $10,000 for the following violations that occur on or after January 1, 1997:

(i) Knowingly and willfully, and on a repeated basis, billing for a clinical diagnostic laboratory test, other than on an assignment-related basis (§ 402.1(c)(1)).

(ii) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(iii) By any durable medical equipment supplier, knowingly and willfully, in violation of section 1834(a)(18)(A), failing to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(iv) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(v) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(vi) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(vii) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assigned-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(viii) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for practitioners specified in section 1842(b)(18)(B) (§ 402.1(c)(11)).

(xix) By any physician, knowingly and willfully presenting, or causing to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§ 402.1(c)(12)).

(x) By any nonparticipating physician who does not accept payment on an assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§ 402.1(c)(13)).

(xi) By any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least $500, knowingly and willfully failing to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§ 402.1(c)(14)).

(xii) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount

other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

(xiii) By any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis—

(A) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(B) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv) (§ 402.1(c)(17)).

(xiv) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§ 402.1(c)(18)).

(xv) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(23)).

(3) CMS or OIG may impose a penalty of not more than $10,000 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient therapy or comprehensive rehabilitation services other than on an assignment-related basis.

(4) CMS or OIG may impose a penalty of not more than $10,000 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient ambulance services other than on an assignment-related basis.

(e) *$15,000*. CMS or OIG may impose a penalty of not more than $15,000 if the seller of a Medicare supplemental policy is not the issuer, for each violation described in paragraphs (f)(2) and (f)(3) of this section (§ 402.1 (c)(25) and (c)(26)).

(f) *$25,000*. CMS or OIG may impose a penalty of not more than $25,000 for each of the following violations:

(1) Issuance of a Medicare supplemental policy that has not been approved by an approved State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C) of the Act (§ 402.1(c)(23)).

(2) Sale or issuance after July 30, 1992, of a Medicare supplemental policy that fails to conform with the NAIC or Federal standards established under section 1882(p) of the Act (§ 402.1(c)(25)).

(3) Failure to make the core group of basic benefits available for sale when selling other Medicare supplemental plans with additional benefits (§ 402.1(c)(26)).

(4) Failure to provide, before sale of a Medicare supplemental policy, an outline of coverage describing the benefits provided by the policy (§ 402.1(c)(26)).

(5) Failure of an issuer of a policy to suspend or reinstate a policy, based on the policy holder's request, during entitlement to or upon loss of eligibility for medical assistance (§ 402.1(c)(27)).

(6) Failure to provide refunds or credits for Medicare supplemental policies as required by section 1882(r)(1)(B) (§ 402.1(c)(28)).

(7) By an issuer of a Medicare supplemental policy—

(i) Substantial failure to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

(ii) Imposition of premiums on enrollees in excess of the premiums approved by the State;

(iii) Action to expel an enrollee for reasons other than nonpayment of premiums; or

(iv) Failure to provide each enrollee, at the time of enrollment, with the specific information provided in section 1882(t)(1)(E)(i) or failure to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii)) (section 1882(t)(2)).

(g) *$100*. CMS or OIG may impose a penalty of not more than $100 for each violation if the person or entity does not furnish an itemized statement to a

Medicare beneficiary within 30 days of the beneficiary's request.

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001]

§ 402.107 Amount of assessment.

A person subject to civil money penalties specified in § 402.1(c) may be subject, in addition, to an assessment. An assessment is a monetary payment in lieu of damages sustained by HHS or a State agency.

(a) The assessment may not be more than twice the amount claimed for each service that was a basis for the civil money penalty, except for the violations specified in paragraph (b) of this section that occur before January 1, 1997.

(b) For the violations specified in this paragraph occurring after January 1, 1997, the assessment may not be more than three times the amount claimed for each service that was the basis for a civil money penalty. The violations are the following:

(1) Knowingly and willfully billing, and on a repeated basis, for a clinical diagnostic laboratory test, other than on an assignment-related basis (§ 402.1(c)(1)).

(2) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(3) By any durable medical equipment supplier, knowingly and willfully failing, in violation of section 1834(a)(18)(A), to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(4) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(5) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(6) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(7) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(i) The supplier does not possess a Medicare supplier number;

(ii) The service is denied in advance; or

(iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(8) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for a person or entity specified in sections 1834(k)(6), 1834(l)(6), or 1842(b)(18)(B) (§ 402.1(c)(11), (c)(31), or (c)(32)).

(9) By any physician, knowingly and willfully presenting, or causing to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§ 402.1(c)(12)).

(10) By any nonparticipating physician who does not accept payment on an assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§ 402.1(c)(13)).

(11) By any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least $500, knowingly and willfully failing to—

(i) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(ii) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§ 402.1(c)(14)).

(12) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

(13) By any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis—

(i) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(ii) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A) (iii) or (iv) (§ 402.1(c)(17)).

(14) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§ 402.1(c)(18)).

(15) By any supplier of durable medical equipment, including suppliers of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(i) The supplier did not possess a Medicare supplier number;

(ii) The service is denied in advance; or

(iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(23)).

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001]

§ 402.109 Statistical sampling.

(a) *Purpose.* CMS or OIG may introduce the results of a statistical sampling study to show the number and amount of claims subject to sanction under this part that the respondent presented or caused to be presented.

(b) *Prima facie evidence.* The results of the statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, constitute prima facie evidence of the number and amount of claims or requests for payment subject to sanction under § 402.1.

(c) *Burden of proof.* Once CMS or OIG has made a prima facie case, the burden is on the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. CMS or OIG then has the opportunity to rebut this evidence.

§ 402.111 Factors considered in determinations regarding the amount of penalties and assessments.

(a) *Basic factors.* In determining the amount of any penalty or assessment, CMS or OIG takes into account the following:

(1) The nature of the claim, request for payment, or information given and the circumstances under which it was presented or given.

(2) The degree of culpability, history of prior offenses, and financial condition of the person submitting the claim or request for payment or giving the information.

(3) The resources available to the person submitting the claim or request for payment or giving the information.

(4) Such other matters as justice may require.

(b) *Criteria to be considered.* As guidelines for taking into account the factors listed in paragraph (a) of this section, CMS or OIG considers the following circumstances:

(1) *Aggravating circumstances of the incident.* An aggravating circumstance is any of the following:

(i) The services or incidents were of several types, occurring over a lengthy period of time.

(ii) There were many of these services or incidents or the nature and circumstances indicate a pattern of claims or requests for payment for these services or a pattern of incidents.

(iii) The amount claimed or requested for these services was substantial.

(iv) Before the incident or presentation of any claim or request for payment subject to imposition of a civil money penalty, the respondent was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services.

(v) There is proof that a respondent engaged in wrongful conduct, other

than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care service. (The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance.)

(2) *Mitigating circumstances.* The following circumstances are mitigating circumstances:

(i) All the services or incidents subject to a civil money penalty were few in number and of the same type, occurred within a short period of time, and the total amount claimed or requested for the services was less than $1,000.

(ii) The claim or request for payment for the service was the result of an unintentional and unrecognized error in the process of presenting claims or requesting payment and the respondent took corrective steps promptly after discovering the error.

(iii) Imposition of the penalty or assessment without reduction would jeopardize the ability of the respondent to continue as a health care provider.

(3) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature are taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to ensure the achievement of the purposes of this part.

(c) *Effect of aggravating or mitigating circumstances.* In determining the amount of the penalty and assessment to be imposed for every service or incident subject to a determination under § 402.1(c)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment is set at an amount sufficiently below the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment is set at an amount at or sufficiently close to the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(d)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed is not less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this section limits the authority of CMS or OIG to settle any issue or case as provided by § 402.19 or to compromise any penalty and assessment as provided by § 402.115.

§ 402.113 When a penalty and assessment are collectible.

A civil money penalty and assessment become collectible after the earliest of the following:

(a) Sixty days after the respondent receives CMS's or OIG's notice of proposed determination under § 402.7, if the respondent has not requested a hearing before an ALJ.

(b) Immediately after the respondent abandons or waives his or her appeal right at any administrative level.

(c) Thirty days after the respondent receives the ALJ's decision imposing a civil money penalty or assessment under § 1005.20(d) of this title, if the respondent has not requested a review before the DAB.

(d) If the DAB grants an extension of the period for requesting the DAB's review, the day after the extension expires if the respondent has not requested the review.

(e) Immediately after the ALJ's decision denying a request for a stay of the effective date under § 1005.22(b) of this title.

(f) If the ALJ grants a stay under § 1005.22(b) of this title, immediately after the judicial ruling is completed.

(g) Sixty days after the respondent receives the DAB's decision imposing a civil money penalty if the respondent has not requested a stay of the decision under § 1005.22(b) of this title.

§ 402.115 Collection of penalty or assessment.

(a) Once a determination by HHS has become final, CMS is responsible for the collection of any penalty or assessment.

(b) The General Counsel may compromise a penalty or assessment imposed under this part, after consultation with CMS or OIG, and the Federal government may recover the penalty or assessment in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The United States or a State agency may deduct the amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

Subpart C—Exclusions [Reserved]

PART 403—SPECIAL PROGRAMS AND PROJECTS

Subpart A [Reserved]

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AUTHORITY: 42 U.S.C. 1395b–3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A [Reserved]

Subpart B—Medicare Supplemental Policies

SOURCE: 47 FR 32400, July 26, 1982, unless otherwise noted.

§ 403.200 Basis and scope.

(a) *Provisions of the legislation.* This subpart implements, in part, section 1882 of the Social Security Act. The intent of that section is to enable Medicare beneficiaries to identify Medicare supplemental policies that do not duplicate Medicare, and that provide adequate, fairly priced protection against expenses not covered by Medicare. The legislation establishes certain standards for Medicare supplemental policies and provides two methods for informing Medicare beneficiaries which policies meet those standards:

(1) Through a State approved program, that is, a program that a Supplemental Health Insurance Panel determines to meet certain minimum requirements for the regulation of Medicare supplemental policies; and

(2) In a State without an approved program, through certification by the Secretary of policies voluntarily submitted by insuring organizations for review against the standards.

(b) *Scope of subpart.* This subpart sets forth the standards and procedures CMS will use to implement the voluntary certification program.

GENERAL PROVISIONS

§ 403.201 State regulation of insurance policies.

(a) The provisions of this subpart do not affect the right of a State to regulate policies marketed in that State.

(b) Approval of a policy under the voluntary certification program, as provided for in § 403.235(b), does not authorize the insuring organization to market a policy that does not conform to applicable State laws and regulations.

§ 403.205 Medicare supplemental policy.

(a) Except as specified in paragraph (e) of this section, Medicare supplemental (or Medigap) policy means a

health insurance policy or other health benefit plan that—

(1) A private entity offers to a Medicare beneficiary; and

(2) Is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare program because of deductibles, coinsurance, or other limitations under Medicare.

(b) The term policy includes both policy form and policy as specified in paragraphs (b)(1) and (b)(2) of this section.

(1) *Policy form.* Policy form is the form of health insurance contract that is approved by and on file with the State agency for the regulation of insurance.

(2) *Policy*. Policy is the contract—

(i) Issued under the policy form; and

(ii) Held by the policy holder.

(c) If the policy otherwise meets the definition in this section, a Medicare supplemental policy includes-

(1) An individual policy;

(2) A group policy;

(3) A rider attached to an individual or group policy; or

(4) As of January 1, 2006, a standalone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries.

(d) Any rider attached to a Medicare supplemental policy becomes an integral part of the basic policy.

(e) Medicare supplemental policy does not include a Medicare Advantage plan, a Prescription Drug Plan under Part D, or any of the other types of health insurance policies or health benefit plans that are excluded from the definition of a Medicare supplemental policy in section 1882(g)(1) of the Act.

[70 FR 4525, Jan. 28, 2005]

§ 403.206 General standards for Medicare supplemental policies.

(a) For purposes of the voluntary certification program described in this subpart, a policy must meet—

(1) The National Association of Insurance Commissioners (NAIC) model standards as defined in § 405.210; and

(2) The loss ratio standards specified in § 403.215.

(b) Except as specified in paragraph (c) of this section, the standards specified in paragraph (a) of this section must be met in a single policy.

(c) In the case of a nonprofit hospital or a medical association where State law prohibits the inclusion of all benefits in a single policy, the standards specified in paragraph (a) of the section must be met in two or more policies issued in conjunction with one another.

§ 403.210 NAIC model standards.

(a) *NAIC model standards* means the National Association of Insurance Commissioners (NAIC) ''Model Regulation to Implement the Individual Accident and Insurance Minimum Standards Act'' (as amended and adopted by the NAIC on June 6, 1979, as it applies to Medicare supplemental policies). Copies of the NAIC model standards can be purchased from the National Association of Insurance Commissioners at 350 Bishops Way, Brookfield, Wisconsin 53004, and from the NIARS Corporation, 318 Franklin Avenue, Minneapolis, Minnesota 55404.

(b) The policy must comply with the provisions of the NAIC model standards, except as follows—

(1) *Policy*, for purposes of this paragraph, means individual and group policy, as specified in § 403.205. The NAIC model standards limit ''policy'' to individual policy.

(2) The policy must meet the loss ratio standards specified in § 403.215.

[47 FR 32400, July 26, 1982; 49 FR 44472, Nov. 7, 1984]

§ 403.215 Loss ratio standards.

(a) The policy must be expected to return to the policyholders, in the form of aggregate benefits provided under the policy—

(1) At least 75 percent of the aggregate amount of premiums in the case of group policies; and

(2) At least 60 percent of the aggregate amount of premiums in the case of individual policies.

(b) For purposes of loss ratio requirements, policies issued as a result of solicitation of individuals through the mail or by mass media advertising are considered individual policies.

STATE REGULATORY PROGRAMS

§ 403.220 Supplemental Health Insurance Panel.

(a) *Membership.* The Supplemental Health Insurance Panel (Panel) consists of—

(1) The Secretary or a designee, who serves as chairperson, and

(2) Four State Commissioners or Superintendents of Insurance appointed by the President. (The terms Commissioner or Superintendent of Insurance include persons of similar rank.)

(b) *Functions.* (1) The Panel determines whether or not a State regulatory program for Medicare supplemental health insurance policies meets and continues to meet minimum requirements specified in section 1882 of the Social Security Act.

(2) The chairperson of the Panel informs the State Commissioners and Superintendents of Insurance of all determinations made under paragraph (b)(1) of this section.

§ 403.222 State with an approved regulatory program.

(a) A State has an approved regulatory program if the Panel determines that the State has in effect under State law a regulatory program that provides for the application of standards, with respect to each Medicare supplemental policy issued in that State, that are equal to or more stringent than those specified in section 1882 of the Social Security Act.

(b) *Policy issued in that State* means—

(1) A group policy, if the holder of the master policy resides in that State; and

(2) An individual policy, if the policy is—

(i) Issued in that State; or

(ii) Issued for delivery in that State.

(c) A policy issued in a State with an approved regulatory program is considered to meet the NAIC model standards in § 403.210 and loss ratio standards in § 403.215.

VOLUNTARY CERTIFICATION PROGRAM: GENERAL PROVISIONS

§ 403.231 Emblem.

(a) The emblem is a graphic symbol, approved by HHS, that indicates that CMS has certified a policy as meeting the requirements of the voluntary certification program, specified in § 403.232.

(b) Unless prohibited by the State in which the policy is marketed, the insuring organization may display the emblem on policies certified under the voluntary certification program.

(c) The manner in which the emblem may be displayed and the conditions and restrictions relating to its use will be stated in the letter with which CMS notifies the insuring organization that a policy has been certified. The insuring organization must comply with these conditions and restrictions.

(d) If a certified policy is issued in a State that later has an approved regulatory program, as provided for in § 403.222, the insuring organization may display the emblem on the policy until the earliest of the following—

(1) When prohibited by State law or regulation.

(2) When the policy no longer meets the requirements for Medicare supplemental policies specified in § 403.206.

(3) The date the insuring organization would be required to submit material to CMS for annual review in order to retain certification, if the State did not have an approved program (see § 403.239).

§ 403.232 Requirements and procedures for obtaining certification.

(a) To be certified by CMS, a policy must meet—

(1) The NAIC model standards specified in § 403.210;

(2) The loss ratio standards specified in § 403.215; and

(3) Any State requirements applicable to a policy—

(i) Issued in that State; or

(ii) Marketed in that State.

(b) An insuring organization requesting certification of a policy must submit the following to CMS for review—

(1) A copy of the policy form (including all the documents that would constitute the contract of insurance that is proposed to be marketed as a certified policy).

(2) A copy of the application form including all attachments.

(3) A copy of the uniform certificate issued under a group policy.

(4) A copy of the outline of coverage, in the form prescribed by the NAIC model standards.

(5) A copy of the Medicare supplement buyers' guide to be provided to all applicants if the buyers' guide is not the CMS/NAIC buyers' guide.

(6) A statement of when and how the outline of coverage and the buyers' guide will be delivered and copies of applicable receipt forms.

(7) A copy of the notice of replacement and statement as to when and how that notice will be delivered.

(8) A list of States in which the policy is authorized for sale. If the policy was approved under a deemer provision in any State, the conditions involved must be specified.

(9) A copy of the loss ratio calculations, as specified in § 403.250.

(10) Loss ratio supporting data, as specified in § 403.256.

(11) A statement of actuarial opinion, as specified in § 403.258.

(12) A statement that the insuring organization will notify the policyholders in writing, within the period of time specified in § 403.245(c), if the policy is identified as a certified policy at the time of sale and later loses certification.

(13) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy meets the requirements specified in paragraph (a) of this section; and

(ii) The information submitted to CMS for review is accurate and complete and does not misrepresent any material fact.

§ 403.235 Review and certification of policies.

(a) CMS will review policies that the insuring organization voluntarily submits, except that CMS will not review a policy issued in a State with an approved regulatory program under § 403.222.

(b) If the requirements specified in § 403.232 are met, CMS will—

(1) Certify the policy; and

(2) Authorize the insuring organization to display the emblem on the policy, as provided for in § 403.231.

(c) If CMS certifies a policy, it will inform all State Commissioners and Superintendents of Insurance of that fact.

§ 403.239 Submittal of material to retain certification.

(a) CMS certification of a policy that continues to meet the standards will remain in effect, if the insuring organization files the following material with CMS no later than the date specified in paragraph (b) or (c) of this section—

(1) Any changes in the material, specified in § 403.232(b), that was submitted for previous certification.

(2) The loss ratio supporting data specified in § 403.256(b).

(3) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy continues to meet the requirements specified in § 403.232(a); and

(ii) The information submitted to CMS for review is accurate and complete and does not misrepresent any material fact.

(b) Except as specified in paragraph (c) of this section, the insuring organization must file the material with CMS no later than June 30 of each year. The first time the insuring organization must file the material is no later than June 30 of the calendar year that follows the year in which CMS—

(1) Certifies a new policy; or

(2) Certifies a policy that lost certification as provided in § 403.245.

(c) If the loss ratio calculation period, used to calculate the expected loss ratio for the last actuarial certification submitted to CMS, ends before the June 30 date of paragraph (b) of this section, the insuring organization must file the material with CMS no later then the last day of that rate calculation period.

§ 403.245 Loss of certification.

(a) A policy loses certification if—

(1) The insuring organization withdraws the policy from the voluntary certification program; or

(2) CMS determines that—

(i) The policy fails to meet the requirements specified in § 403.232(a); or

(ii) The insuring organization has failed to meet the requirements for submittal of material specified in § 403.239.

(b) If a policy loses its certification, CMS will inform all State Commissioners and Superintendents of Insurance of that fact.

(c) If a policy that displays the emblem, or that has been marketed as a certified policy without the emblem, loses certification, the insuring organization must notify each holder of the policy, or of a certificate issued under the policy, of that fact. The notice must be in writing and sent by the earlier of—

(1) The date of the first regular premium notice after the date the policy loses its certification; or

(2) 60 days after the date the policy loses its certification.

§ 403.248 Administrative review of CMS determinations.

(a) This section provides for administrative review if CMS determines—

(1) Not to certify a policy; or

(2) That a policy no longer meets the standards for certification.

(b) If CMS makes a determination specified in paragraph (a) of this section, it will send a notice to the insuring organization containing the following information:

(1) That CMS has made such a determination.

(2) The reasons for the determination.

(3) That the insuring organization has 30 days from the date of the notice to—

(i) Request, in writing, an administrative review of the CMS determination; and

(ii) Submit additional information to CMS for review.

(4) That, if the insuring organization requests an administrative review, CMS will conduct the review, as provided for in paragraph (c) of this section.

(5) That, in a case involving loss of certification, the CMS determination will go into effect 30 days from the date of the notice, unless the insuring organization requests an administrative review. If the insuring organization requests an administrative review, the policy retains its certification until CMS makes a final determination.

(c) If the insuring organization requests an administrative review, CMS will conduct the review as follows—

(1) A CMS official, not involved in the initial CMS determination, will initiate and complete an administrative review within 90 days of the date of the notice provided for in paragraph (b) of this section.

(2) The official will consider—

(i) The original material submitted to CMS for review, as specified in § 403.232(b) or § 403.239(a); and

(ii) Any additional information, that the insuring organization submits to CMS.

(3) Within 15 days after the administrative review is completed, CMS will inform the insuring organization in writing of the final decision, with an explanation of the final decision.

(4) If the final decision is that a policy lose its certification, the loss of certification will go into effect 15 days after the date of CMS's notice informing the insuring organization of the final decision.

VOLUNTARY CERTIFICATION PROGRAM: LOSS RATIO PROVISIONS

§ 403.250 Loss ratio calculations: General provisions.

(a) *Basic formula*. The expected loss ratio is calculated by determining the ratio of benefits to premiums.

(b) *Calculations*. The insuring organization must calculate loss ratios according to the provisions of §§ 403.251, 403.253, and 403.254.

§ 403.251 Loss ratio date and time frame provisions.

(a) *Initial calculation date* means the first date of the period that the insuring organization uses to calculate the policy's expected loss ratio.

(1) The initial calculation date may be before, the same as, or after the date the insuring organization sends the policy to CMS for review, except—

(2) The initial calculation date must not be earlier than January 1 of the calendar year in which the policy is sent to CMS.

(b) *Loss ratio calculation period* means the period beginning with the initial calculation date and ending with the

last day of the period for which the insuring organization calculates the policy's scale of premiums.

(c) To calculate ''present values'', the insuring organization may ignore discounting (an actuarial procedure that provides for the impact of a variety of factors, such as lapse of policies) for loss ratio calculation periods not exceeding 12 months.

§ 403.253 Calculation of benefits.

(a) *General provisions.* (1) Except as provided for in paragraph (a)(2) of this section, calculate the amount of ''benefits'' by—

(i) Adding the present values on the initial calculation date of—

(A) Expected incurred benefits in the loss ratio calculation period, to—

(B) The total policy reserve at the last day of the loss ratio calculation period: and

(ii) Subtracting the total policy reserve on the initial calculation date from the sum of these values.

(2) To calculate the amount of ''benefits'' in the case of community or pool rated individual or group policies rerated on an annual basis, calculate the expected incurred benefits in the loss ratio calculation period.

(b) *Calculation of total policy reserve*—(1) *Option for calculation.* The insuring organization must calculate ''total policy reserve'' according to the provisions of paragraph (b) (2) or (3) of this section.

(2) *Total policy reserve: Federal provisions.* (i) ''Total policy reserve'' means the sum of—

(A) Additional reserve; and

(B) The reserve for future contingent benefits.

(ii) *Additional reserve* means the amount calculated on a net level reserve basis, using appropriate values to account for lapse, mortality, morbidity, and interest, that on the valuation date represents—

(A) The present value of expected incurred benefits over the loss ratio calculation period; less—

(B) The present value of expected net premiums over the loss ratio calculation period.

(iii) *Net premium* means the level portion of the gross premium used in calculating the additional reserve. On the day the policy is issued, the present value of the series of those portions equals the present value of the expected incurred claims over the period that the gross premiums are computed to provide coverage.

(iv) *Reserve for future contingent benefits* means the amounts, not elsewhere included, that provide for the extension of benefits after insurance coverage terminates. These benefits—

(A) Are predicated on a health condition existing on the date coverage ends;

(B) Accrue after the date coverage ends; and

(C) Are payable after the valuation date.

(3) *Total policy reserve: State provisions.* ''Total policy reserve'' means the total policy reserve calculated according to appropriate State law or regulation.

§ 403.254 Calculation of premiums.

(a) *General provisions.* To calculate the amount of ''premiums'', calculate the present value on the initial calculation date of expected earned premiums for the loss ratio calculation period.

(b) *Specific provisions.* (1) *Earned premium* for a given period means—

(i) Written premiums for the period; plus—

(ii) The total premium reserve at the beginning of the period; less—

(iii) The total premium reserve at the end of the period.

(2) *Written premiums in a period* means—

(i) Premiums collected in that period; plus—

(ii) Premiums due and uncollected at the end of that period; less—

(iii) Premiums due and uncollected at the beginning of that period.

(3) *Total premium reserve* means the sum of—

(i) The unearned premium reserve;

(ii) The advance premium reserve; and

(iii) The reserve for rate credits.

(4) *Unearned premium reserve* means the portion of gross premiums due that provide for days of insurance coverage after the valuation date.

(5) *Advance premium reserve* means premiums received by the insuring organization that are due after the valuation date.

(6) *Reserve for rate credits* means rate credits on a group policy that—

(i) Accrue by the valuation date of the policy; and

(ii) Are paid or credited after the valuation date.

§ 403.256 Loss ratio supporting data.

(a) For purposes of requesting CMS certification under § 403.232, the insuring organization must submit the following loss ratio data to CMS for review—

(1) A statement of why the policy is to be considered, for purposes of the loss ratio standards, an individual or a group policy.

(2) The earliest age at which policyholders can purchase the policy.

(3) The general marketing method and the underwriting criteria used for the selection of applicants to whom coverage is offered.

(4) What policies are to be included under the one policy form, by the dates the policies are issued.

(5) The loss ratio calculation period.

(6) The scale of premiums for the loss ratio calculation period.

(7) The expected level of earned premiums in the loss ratio calculation period.

(8) The expected level of incurred claims in the loss ratio calculation period.

(9) A description of how the following assumptions were used in calculating the loss ratio.

(i) Morbidity.

(ii) Mortality.

(iii) Lapse.

(iv) Assumed increases in the Medicare deductible.

(v) Impact of inflation on reimbursement per service.

(vi) Interest.

(vii) Expected distribution, by age and sex, of persons who will purchase the policy in the coming year.

(viii) Expected impact on morbidity by policy duration of—

(A) The process used to select insureds from among those that apply for a policy; and

(B) Pre-existing condition clauses in the policy.

(b) For purposes of requesting continued CMS certification under § 403.239(a), the insuring organization must submit the following to CMS—

(1) A description of all changes in the loss ratio data, specified in paragraph (a) of this section, that occurred since CMS last reviewed the policy.

(2) The past loss ratio experience for the policy, including the experience of all riders and endorsements issued under the policy. The loss ratio experience data must include earned premiums, incurred claims, and total policy reserves that the insuring organization calculates—

(i) For all years of issue combined; and

(ii) Separately for each calendar year since CMS first certified the policy.

§ 403.258 Statement of actuarial opinion.

(a) For purposes of certification requests submitted under § 403.232(b) and subsequent review as specified in § 403.239(a), *statement of actuarial opinion* means a signed declaration in which a qualified actuary states that the assumptions used in calculating the expected loss ratio are appropriate and reasonable, taking into account actual policy experience, if any, and reasonable expectations.

(b) *Qualified actuary* means—

(1) A member in good standing of the American Academy of Actuaries; or

(2) A person who has otherwise demonstrated his or her actuarial competence to the satisfaction of the Commissioner or Superintendent of Insurance of the domiciliary State of the insuring organization.

Subpart C—Recognition of State Reimbursement Control Systems

SOURCE: 51 FR 15492, Apr. 24, 1986, unless otherwise noted.

§ 403.300 Basis and purpose.

(a) *Basis.* This subpart implements section 1886(c) of the Act, which authorizes payment for Medicare inpatient hospital services in accordance with a State's reimbursement control system rather than under the Medicare

reimbursement principles as described in CMS's regulations and instructions.

(b) *Purpose.* Contained in this subpart are—

(1) The basic requirements that a State reimbursement control system must meet in order to be approved by CMS;

(2) A description of CMS's review and evaluation procedures; and

(3) The conditions that apply if the system is approved.

§ 403.302 Definitions.

For purposes of this subpart—

Chief executive officer of a State means the Governor of the State or the Governor's designee.

Existing demonstration project refers to demonstration projects approved by CMS under the authority of section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 (note)) and in effect on April 20, 1983 (the date of the enactment of Pub. L. 98–21 (Social Security Amendments of 1983)).

Federal hospital means a hospital that is administered by, or that is under exclusive contract with, the Department of Defense, the Veterans Administration, or the Indian Health Service.

State system or *system* refers to a State reimbursement control system that is approved by CMS under the authority of section 1886(c) of the Act and that satisfies the requirements described in this subpart.

§ 403.304 Minimum requirements for State systems—discretionary approval.

(a) *Discretionary approval by CMS.* CMS may approve Medicare payments under a State system, if CMS determines that the system meets the requirements in paragraphs (b) and (c) of this section and, if applicable paragraph (d) of this section.

(b) *Requirements for State system.* (1) An application for approval of the system must be submitted to CMS by the Chief Executive Officer of the State.

(2) The State system must apply to substantially all non-Federal acute care hospitals in the State.

(3) All hospitals covered by the system must have and maintain a utilization and quality control review agreement with a Quality Improvement Organization, as required under section 1866(a)(1)(F) of the Act and § 466.78(a) of this chapter.

(4) Federal hospitals must be excluded from the State system.

(5) Nonacute care or specialty hospital (such as rehabilitation, psychiatric, or children's hospitals) may, at the option of the State, be excluded from the State system.

(6) The State system must apply to at least 75 percent of all revenues or expenses—

(i) For inpatient hospital services in the State; and

(ii) For inpatient hospital services under the State's Medicaid plan.

(7) Under the system, HMOs and competitive medical plans (CMPs), as defined by section 1876(b) of the Act and part 417 of this chapter, must be allowed to negotiate payment rates with hospitals.

(8) The system must limit hospital charges for Medicare beneficiaries to deductibles, coinsurance or non-covered services.

(9) Unless a waiver is granted by CMS under § 489.23 of this chapter, the system must prohibit payment, as required under section 1862(a)(14) of the Act and § 405.310(m) of this chapter, for nonphysician services provided to hospital inpatients under Part B of Medicare.

(10) The system must require hospitals to submit Medicare cost reports or approved reports in lieu of Medicare cost reports as required.

(11) The system must require—

(i) Preparation, collection, or retention by the State of reports (such as financial, administrative, or statistical reports) that may be necessary, as determined by CMS, to review and monitor the State's assurances; and

(ii) Submission of the reports to CMS upon request.

(12) The system must provide hospitals an opportunity to appeal errors that they believe have been made in the determination of their payment rates. The system, if it is prospective may not permit providers to file administrative appeals that would result

in a retroactive revision of prospectively determined payment rates.

(c) *Satisfactory assurances.* The State must provide to CMS satisfactory assurance as to the following:

(1) The system provides for equitable treatment of hospital patients and hospital employees.

(2) The system provides for equitable treatment of all entities that pay hospitals for inpatient hospital services, including Federal and State programs. Under the requirement, the following conditions must be met:

(i) Both the Medicare and Medicaid programs must participate under the system.

(ii) The State must assure equitable and uniform treatment under the system of third-party payors of inpatient hospital services in terms of opportunity. Equitable opportunity must include, but need not be limited to, participation in the system and availability of discounts. Criteria under which discounts are made available must be equitably and uniformly applied to all payors, except for discounts negotiated by HMOs and CMPs. Discounts available to HMOs and CMPs as result of their statutory right to negotiate payment rates independently of a State system, as described in paragraph (b)(7) of this section, need not be available to other payors.

(iii) The State must assure that all third-party payors that participate under the system share in the system's risks and benefits.

(3) The amount of Medicare payments made under the system over 36-month periods may not exceed the amount of Medicare payment that would otherwise have been made under the Medicare principles of reimbursement for Medicare items and services had the State system not been in effect. States must submit the assurance and supporting data as required by § 403.320 to document that the payment limit is not exceeded. States that have an existing Medicare demonstration project in effect on April 20, 1983, and that have requested approval of a State system under section 1886(c)(4) of the Act, may elect to have the effectiveness of the State system under this paragraph judged on the basis of the State system's rate of increase or inflation in Medicare inpatient hospital payments as compared to the national rate of increase or inflation for such payments during the three cost reporting periods of the hospitals in the State beginning on or after October 1, 1983.

(d) *Additional cost-effectiveness assurance.* If the assurances and supporting data required under paragraph (c)(3) of this section are insufficient to provide assurance satisfactory to CMS regarding the cost-effectiveness of a State system, the State may additionally submit one of the following assurances in order to meet the cost-effectiveness test:

(1) *State responsibility for excess payments.* The State must agree that each month Medicare intermediaries will disburse to the State's hospital Federal funds that in the aggregate equal no more than would have been disbursed in the absence of the State system. Any additional funds necessary to pay hospitals for Medicare services required by the State system will be paid to the intermediaries by the State. These additional amounts will be refunded to the State by the intermediaries to the extent that, in subsequent months, the State system requires a smaller aggregate payment for Medicare services than would have been paid in the absence of the State system.

(2) *Limitations on payments.* (i) The State must agree that if its projections exceed what Medicare would pay in any particular period, the State and CMS will establish and agreed upon payment schedule that will limit payments under the State system based on a predetermined percentage relationship between projected State payments and what payments would have been under Medicare.

(ii) If deviation from the predetermined relationship described in paragraph (d)(2)(i) of this section occurs, the State must further agree that—

(A) Medicare payments would be capped automatically at payment levels based on the rates used for the Medicare prospective payment system and the State would be required to pay the difference to individual hospitals in its system; or

(B) The State may provide by legislation or legally binding regulations that

any reduced payments to hospitals under the system that result from this cost-effectiveness assurance will constitute full and final payment for hospital services furnished to Medicare beneficiaries for the period covered by these reduced payments.

§ 403.306 Additional requirements for State systems—mandatory approval.

(a) *General policy*—(1) *Mandatory approval.* HFCA will approve an application for Medicare reimbursement under a State system if the system meets all of the requirements of § 403.304 and of paragraph (b) of this section.

(2) *Exception.* CMS may approve an application if the State system meets all of the requirements of § 403.304 but only some of the requirements of paragraph (b) of this section.

(b) *Additional requirements*—(1) *Operation of system.* The system must—

(i) Be operated directly by the State or by entity designated under State law;

(ii) Provide for payments to hospitals using a methodology under which—

(A) Prospectively determined payment rates are established; and

(B) Exceptions, adjustments, and methods for changes in methodology are set forth;

(iii) Provide that a change by the State in the system that has the effect of materially changing payments to hospitals can take effect only upon 60 days notice to CMS and to the hospitals likely to be materially affected by the change and upon CMS's approval of the change.

(2) *Satisfactory assurances*—(i) *Admissions practice.* The State must assure that the operation of the system will not result in any change in hospital admission practices that result in—

(A) A significant reduction in the proportion of patients receiving hospital services covered under the system who have no third-party coverage and who are unable to pay for hospital services;

(B) A significant reduction in the proportion of individuals admitted to hospitals for inpatient hospital services for which payment is less, or is likely to be less, than the anticipated charges for or cost of the services;

(C) A refusal to admit patients who would be expected to require unusually costly or prolonged treatment for reasons other than those related to the appropriateness of the care available at the hospital; or

(D) A refusal to provide emergency services to any person who is in need of emergency services, if the hospital provides the services.

(ii) *Consultation with local government officials.* The State must provide documentation that it has consulted with local government officials concerning the impact of the system on publicly owned or operated hospitals.

§ 403.308 State systems under demonstration projects—mandatory approval.

CMS will approve an application from a State for a State system if—

(a) The system was in effect prior to April 20, 1983 under an existing demonstration project; and

(b) The minimum requirements and assurances for approval of a State system are met under § 403.304 (b)(1)–(10) and § 403.304(c), and, if appropriate § 403.304(d).

§ 403.310 Reduction in payments.

(a) *General rule.* If CMS determines that the satisfactory assurances required of a State under § 403.304(c) and, if applicable, § 403.304(d) have not been met, or will not be met, with respect to any 36-month period, CMS will reduce Medicare payments to individual hospitals being reimbursed under the State's system or, if applicable, under the Medicare payment system, in an amount equal to the amount by which the Medicare payments under the system exceed the amount of Medicare payments to such hospitals that otherwise would have been made not using the State system. The amount of the recoupment will include, when appropriate, interest charges computed in accordance with § 405.378 of this chapter.

(b) *Recoupment procedures.* The amount of the overpayment will be recouped on a proportionate basis from each of those hospitals that received payments under the State system that exceeded the payments they would

have received under the Medicare payment system. Each hospital's share of the aggregate excess payment will be determined on the basis of a comparison of the hospital's proportionate share of the aggregate payment received under the State system that is in excess of what the aggregate payment would have been under the Medicare payment system. Recoupments may be accomplished by a hospital's direct payment to the Medicare program or by offsets to future payments made to the hospital.

(c) *Alternative recoupment procedures.* As an alternative to the recoupment procedures described in paragraph (b) of this section and subject to CMS's acceptance, the State may provide, by legislation or legally binding regulations, procedures for the recoupment of the amount of payments that exceed the amount of payments that otherwise would have been paid by Medicare if the State system had not been in effect.

(d) *Rule for existing Medicare demonstration projects.* In cases of existing Medicare demonstration projects where the expenditure test is to be applied by a rate of increase factor, the amount of the excess payment will be determined, for the three hospital cost reporting periods beginning before October 1, 1986, by a comparison of the State system's rate of increase to the national rate of increase. Recoupment of excessive payments will be assessed and recouped as described in this section.

[51 FR 15492, Apr. 24, 1986, as amended at 61 FR 63748, Dec. 2, 1996]

§ 403.312 Submittal of application.

The Chief Executive Officer of the State is responsible for—

(a) Submittal of the application to CMS for approval; and

(b) Supplying the assurances and necessary documentation as required under §§ 403.304 through 403.308.

§ 403.314 Evaluation of State systems.

CMS will evaluate all State applications for approval of State systems and notify the State of its determination within 60 days.

§ 403.316 Reconsideration of certain denied applications.

(a) *Request for reconsideration.* If CMS denies an application for a State system, the State may request that CMS reconsider the denial if the State believes that its system meets all of the requirements for mandatory approval under §§ 403.304 and 403.306 or, in the case of a State with a system operating under an existing demonstration project, the applicable requirements of §§ 403.304 and 403.308.

(b) *Time limit.* (1) The State must submit its request for reconsideration within 60 days after the date of CMS's notice that the application was denied.

(2) CMS will notify the State of the results of its reconsideration within 60 days after it receives the request for reconsideration.

§ 403.318 Approval of State systems.

(a) *Approval agreement.* If CMS approves a State system, a written agreement will be executed between CMS and the Chief Executive Officer of the State. The agreement must incorporate any terms of the State's application for approval of the system as agreed to by the parties and, as a minimum, must contain provisions that require the following:

(1) The system is operated directly by the State or an entity designated by State law.

(2) For purposes of the Medicare program, the State's system applies only to Medicare payments for inpatient, and if applicable, outpatient hospital services.

(3) The system conforms to applicable Medicare law and regulations other than those relating to the amount of reimbursement for inpatient hospital services, or for inpatient and outpatient services, whichever the State system covers. Applicable regulations include, for example, those describing Medicare benefits and entitlement requirements for program beneficiaries, as explained in parts 406 and 409 of this chapter; the requirements at part 405, subpart J of this chapter specifying conditions of participation for hospitals; the requirements at part 405, subparts A, G, and S of this chapter on Medicare program administration; and

all applicable fraud and abuse regulations contained in titles 42 and 45 of the CFR.

(4) The State must obtain CMS's approval of the State's reporting forms and of provider cost reporting forms or other forms that have not been approved by CMS but that are necessary for the collection of required information.

(b) *Effective date.* An approved State system may not be effective earlier than the date of the approval agreement, which may not be retroactive.

§ 403.320 CMS review and monitoring of State systems.

(a) *General rule.* The State must submit an assurance and detailed and quantitative studies of provider cost and financial data and projections to support the effectiveness of its system, as required by paragraphs (b) and (c) of this section.

(b) *Required information.* (1) Under § 403.304(c)(3) an assurance is required that the system will not result in greater payments over a 36-month period than would have otherwise been made under Medicare not using such system. If a State that has an existing demonstration project in effect on April 20, 1983 elects under § 403.304(c)(3) to have the effectiveness of its system judged on the basis of a rate of increase factor, the State must submit an assurance that its rate of increase or inflation in inpatient hospital payments does not exceed, for that portion of the 36-month period that is subject to this test, the national rate of increase or inflation in Medicare inpatient hospital payments. The election of the rate of increase test applies only to the three cost reporting periods beginning on or after October 1, 1983. At the end of these cost reporting periods, the State must assure, beginning with the first month after the expiration of the third cost reporting period beginning after October 1, 1983, that payments under its system will not exceed over the remainder of the 36-month period what Medicare payments would have been.

(2) Estimates and data are required to support the State's assurance, required under § 403.304(c)(3), that expenditures under the State system will not exceed what Medicare would have paid over a 36-month period. The estimates and projections of what Medicare would have otherwise paid must take into account all the Medicare reimbursement principles in effect at the time and, for any period in which payments either exceed or are less than Medicare levels, the values of interest the Medicare Trust Fund earned, or would have earned, on these amounts. Upon application for approval, the State must submit projections for each hospital for the first 12-month period covered by the assurance, in both the aggregate and on a per discharge basis, of Medicare inpatient expenditures under Medicare principles of reimbursement and parallel projections of Medicare inpatient expenditures under the State's system and the resulting cost or savings to Medicare. The State must also submit separate statewide projections for each year of the 36-month period, in both the aggregate and on a weighted average discharge basis, of inpatient expenditures under the State system and under the Medicare principles of reimbursement.

(3) The projection submitted under paragraph (b)(2) of this section must include a detailed description of the methodology and assumptions used to derive the expenditure amounts under both systems. In instances where the assumptions are different under the projections cited in paragraph (b)(2) of this section, the State must provide a detailed explanation of the reasons for the differences. At a minimum, the following separate data and assumptions are to be included in the projections for the Medicare principles and for the State's system.

(i) The State system base year and the Medicare allowable and reimbursable cost of each hospital that the State used to develop the projections, including the amount of estimated pass through costs.

(ii) The categories of costs that are included in the State system and are reimbursed differently under the State system than under the Medicare system.

(iii) The number of Medicare and total base year discharges and admissions for each hospital.

(iv) The rate of change factor (and the method of application of this factor) used to project the base year costs over the 36-month period to which the assurance would apply.

(v) Any allowance for anticipated growth in the amount of services from the base year (if applicable, the allowance must be presented in separate estimates for population increases or for increases in rates of admissions or both).

(vi) Any adjustment in which the State is permitted by CMS to take into account previous reductions in the Medicare payment amounts that were the result of the effectiveness of the State's system even though Medicare was not a part of that system.

(vii) Appropriate recognition and projection of the time value of trust fund expenditures for the period the State system expenditures were either less than or exceeded the Medicare system payments.

(viii) States applying under a rate of increase effectiveness test under § 403.304(c)(3) must also submit data projecting the parallel rates of increase during the requisite period.

(4) The projections must include both the aggregate payments and the payments per discharge for the individual hospitals and for the State as a whole.

(5) On a case-by-case basis. CMS may require additional data and documentation as needed to complete its review and monitoring.

(6) For existing Medicare demonstration projects in effect on April 20, 1983, the assurance and data as required by paragraphs (a) and (b) of this section, if appropriate, may be based on aggregate payments or payments per inpatient admission or discharge. CMS will judge the effectiveness of these systems on the basis of the rate of increase or inflation in Medicare inpatient hospital payments compared to the national rate of increase or inflation for such payments during the State's hospitals' three cost reporting periods beginning on or after October 1, 1983. The data submitted by the State for the period subject to the rate of increase test must include the rate of increase projection for that particular period of time. For the subsequent period of time, the State must assure that payments under its system will not exceed what Medicare payments would have been, as described in § 403.304(c)(3).

(7) If the amount of Medicare payments under the State system exceeds what would have been paid under the Medicare reimbursement principles in any given year, the State must also submit quantitative evidence that the system will result in expenditures that do not exceed what Medicare expenditures would have been over the 36 month period beginning with the first month that the State system is operating. For a State that has an existing demonstration project in effect on April 20, 1983, and that elects under § 403.304(c)(3) to have a rate of increase test apply, if the State's rate of increase or inflation exceeds the national rate of increase or inflation in a given year, the State must submit quantitative evidence that, over 36 months, its payments will not exceed the national rate of increase or inflation. Furthermore, if payments under the State's system must be compared to actual Medicare expenditures, at the end of the third cost reporting period, as described in paragraph (b)(1) of this section, and payments under the State's system exceed what Medicare would have paid in a given year, the State must submit quantitative evidence that, over 36 months, payments under its system will not exceed what Medicare would have paid.

(c) *Review of assurances regarding expenditures.* CMS will review the State's assurances and data submitted under this section, as a prerequisite to the approval of the State's system. CMS will compare the State's projections of payment amounts to CMS data in order to determine if the State's assurance is reasonable and fully supportable. If the CMS data indicate that the State's system would result in payment amounts that would be more then that which would have been paid under the Medicare principles, the State's assurances would not be acceptable. For States applying in accordance with § 403.308, if CMS data indicate that the State's system would result in a rate of increase or inflation that would be more than the national rate of increase or inflation, the State's assurances would not be acceptable.

(d) *Medicaid upper limit.* In accordance with § 447.253 of this chapter, the State system may not result in aggregate payments for Medicaid inpatient hospital services that would exceed the amount that would have otherwise have been paid under the Medicare principles as applied through the State system.

(e) *Monitoring of Medicare expenditures.* CMS will monitor on a quarterly basis expenditures under the State's system as compared to what Medicare expenditures would have been if the system had not been in effect. If CMS determines at any time that the payments made under the State's system exceed the States' projections, as established by the satisfactory assurances required under § 403.304(c) and, if appropriate, the predetermined percentage relationship of the payments as required under § 403.304(d). CMS will—

(1) Conclude that payments under the State system over a 36-month period will exceed what Medicare would have paid:

(2) Terminate the waiver; and

(3) Recoup overpayments to the affected hospitals in accordance with the procedures described in § 403.310.

§ 403.321 State systems for hospital outpatient services.

CMS may approve a State's application for approval of an outpatient system if the following conditions are met:

(a) The State's inpatient system is approved.

(b) The State's outpatient application meets the requirements and assurances for an inpatient system described in § 403.304 (b) and (c), and § 403.306 (b)(1) and (b)(2)(ii).

(c) The State submits a separate application that provides separate assurances and estimates and data in further support of its assurance submitted under paragraph (b)(1) of § 403.320, as follows:

(1) Upon application for approval, the State must submit estimates and data that include, but are not limited to, projections for the first 12-month period covered by the assurance for each hospital, in both the aggregate and on an average cost per service and payment basis, of Medicare outpatient expenditures under Medicare principles of reimbursement; parallel projections of Medicare outpatient expenditures under the State system; and the resulting cost or savings to Medicare independent of the State system for hospital inpatient services.

(2) The State must submit separate statewide projections for each year of the 36-month period of the aggregate outpatient expenditures for each system. The projections submitted under this paragraph must—

(i) Comply with the requirements of paragraphs (b) (3) and (5) of § 403.320 regarding a detailed description of the methodology used to derive the expenditure amounts:

(ii) Include the data and assumptions set forth in paragraphs (b)(3) (i), (ii), (iii), (iv), and (v) of § 403.320; and

(iii) Include any assumption the State has adopted for establishing the number of Medicare and total base year outpatient services for each hospital.

(3) The State must provide a detailed explanation of the reasons for any difference between the data or assumptions used for the separate projections.

§ 403.322 Termination of agreements for Medicare recognition of State systems.

(a) *Termination of agreements.* (1) CMS may terminate any approved agreement if it finds, after the procedures described in this paragraph are followed that the State system does not satisfactorily meet the requirements of section 1886(c) of the Act or the regulations in this subpart. A termination must be effective on the last day of a calendar quarter.

(2) CMS will give the State reasonable notice of the proposed termination of an agreement and of the reasons for the termination at least 90 days before the effective date of the termination.

(3) CMS will give the State the opportunity to present evidence to refute the finding.

(4) CMS will issue a final notice of termination upon a final review and determination on the State's evidence.

(b) *Termination by State.* A State may voluntarily terminate a State system by giving CMS notice of its intent to

terminate. A termination must be effective on the last day of a calendar quarter. The State must notify CMS of its intent to terminate at least 90 days before the effective date of the termination.

Subpart D [Reserved]

Subpart E—Beneficiary Counseling and Assistance Grants

SOURCE: 59 FR 51128, Oct. 7, 1994, unless otherwise noted.

§ 403.500 Basis, scope, and definition.

(a) *Basis*. This subpart implements, in part, the provisions of section 4360 of Public Law 101–508 by establishing a minimum level of funding for grants made to States for the purpose of providing information, counseling, and assistance relating to obtaining adequate and appropriate health insurance coverage to individuals eligible to receive benefits under the Medicare program.

(b) *Scope of subpart*. This subpart sets forth the following:

(1) Conditions of eligibility for the grant.

(2) Minimum levels of funding for those States qualifying for the grants.

(3) Reporting requirements.

(c) *Definition*. For purposes of this subpart, the term ''State'' includes (except where otherwise indicated by the context) the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

§ 403.501 Eligibility for grants.

To be eligible for a grant under this subpart, the State must have an approved Medicare supplemental regulatory program under section 1882 of the Act and submit a timely application to CMS that meets the requirements of—

(a) Section 4360 of Public Law 101–508 (42 USC 1395b-4);

(b) This subpart; and

(c) The applicable solicitation for grant applications issued by CMS.

§ 403.502 Availability of grants.

CMS awards grants to States subject to availability of funds, and if applicable, subject to the satisfactory progress in the State's project during the preceding grant period. The criteria by which progress is evaluated and the performance standards for determining whether satisfactory progress has been made are specified in the terms and conditions included in the notice of grant award sent to each State. CMS advises each State as to when to make application, what to include in the application, and provides information as to the timing of the grant award and the duration of the grant award. CMS also provides an estimate of the amount of funds that may be available to the State.

[65 FR 34985, June 1, 2000]

§ 403.504 Number and size of grants.

(a) *General*. For available grant funds, up to and including $10,000,000, grants will be made to States according to the terms and formula in paragraphs (b) and (c) of this section. For any available grant funds in excess of $10,000,000, distribution of grants will be at the discretion of CMS, and will be made according to criteria that CMS will communicate to the States via grant solicitation. CMS will provide information to each State as to what must be included in the application for grant funds. CMS awards the following type of grants:

(1) New program grants.

(2) Existing program enhancement grants.

(b) *Grant Award*. Subject to the availability of funds, each eligible State that submits an acceptable application receives a grant that includes a fixed amount (minimum funding level) and a variable amount.

(1) A fixed portion is awarded to States in the following amounts:

(i) Each of the 50 States, $75,000.

(ii) The District of Columbia, $75,000.

(iii) Puerto Rico, $75,000.

(iv) American Samoa, $25,000.

(v) Guam, $25,000.

(vi) The Virgin Islands, $25,000.

(2) A variable portion, which is based on the number and location of Medicare beneficiaries residing in the State is awarded to each State. The variable amount a particular State receives is determined as set forth in paragraph (c) of this section.

(c) *Calculation of variable portion of the grant.* (1) CMS bases the variable portion of the grant on—

(i) The amount of available funds, and

(ii) A comparison of each State with the average of all of the States (except the State being compared) with respect to three factors that relate to the size of the State's Medicare population and where that population resides.

(2) The factors CMS uses to compare States' Medicare populations comprise separate components of the variable amount. These factors, and the extent to which they each contribute to the variable amount, are as follows:

(i) Approximately 75 percent of the variable amount is based on the number of Medicare beneficiaries living in the State as a percentage of all Medicare beneficiaries nationwide.

(ii) Approximately 10 percent of the variable amount is based on the percentage of the State's total population who are Medicare beneficiaries.

(iii) Approximately 15 percent of the variable amount is based on the percentage of the State's Medicare beneficiaries that reside in rural areas (''rural areas'' are defined as all areas not included within a Metropolitan Statistical Area).

(3) Based on the foregoing four factors (that is, the amount of available funds and the three comparative factors), CMS determines a variable rate for each participating State for each grant period.

(d) *Submission of revised budget.* A State that receives an amount of grant funds under this subpart that differs from the amount requested in the budget submitted with its application must submit a revised budget to CMS, along with its acceptance of the grant award, that reflects the amount awarded.

[59 FR 51128, Oct. 7, 1994, as amended at 65 FR 34986, June 1, 2000]

§ 403.508 Limitations.

(a) *Use of grants.* Except as specified in paragraph (b) of this section, and in the terms and conditions in the notice of grant award, a State that receives a grant under this subpart may use the grant for any reasonable expenses for planning, developing, implementing, and/or operating the program for which the grant is made as described in the solicitation for application for the grant.

(b) *Maintenance of effort.* A State that receives a grant to supplement an existing program (that is, an existing program enhancement grant)—

(1) Must not use the grant to supplant funds for activities that were conducted immediately preceding the date of the initial award of a grant made under this subpart and funded through other sources (including in-kind contributions).

(2) Must maintain the activities of the program at least at the level that those activities were conducted immediately preceding the initial award of a grant made under this subpart.

[59 FR 51128, Oct. 7, 1994, as amended at 65 FR 34986, June 1, 2000]

§ 403.510 Reporting requirements.

A State that receives a grant under this subpart must submit at least one annual report to CMS and any additional reports as CMS may prescribe in the notice of grant award. CMS advises the State of the requirements concerning the frequency, timing, and contents of reports in the notice of grant award that it sends to the State.

§ 403.512 Administration.

(a) *General.* Administration of grants will be in accordance with the provisions of this subpart, 45 CFR part 92 (''Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments''), 45 CFR 74.4, the terms of the solicitation, and the terms of the notice of grant award. Except for the minimum funding levels established by § 403.504(b)(1), in the event of conflict between a provision of the notice of grant award, any provision of the solicitation, or of any regulation enumerated in 45 CFR 74.4 or in part 92, the terms of the notice of grant award control.

(b) *Notice.* CMS provides notice to each applicant regarding CMS's decision on an application for grant funding under § 403.504.

(c) *Appeal.* Any applicant for a grant under this subpart has the right to appeal CMS's determination regarding its

application. Appeal procedures are governed by the regulations at 45 CFR part 16 (Procedures of the Departmental Grant Appeals Board).

Subpart F [Reserved]

Subpart G—Religious Nonmedical Health Care Institutions—Benefits, Conditions of Participation, and Payment

SOURCE: 64 FR 67047, Nov. 30, 1999, unless otherwise noted.

§ 403.700 Basis and purpose.

This subpart implements sections 1821; 1861(e), (y), and (ss); 1869; and 1878 of the Act regarding Medicare payment for inpatient hospital or posthospital extended care services furnished to eligible beneficiaries in religious nonmedical health care institutions.

§ 403.702 Definitions and terms.

For purposes of this subpart, the following definitions and terms apply:

Election means a written statement signed by the beneficiary or the beneficiary's legal representative indicating the beneficiary's choice to receive nonmedical care or treatment for religious reasons.

Excepted medical care means medical care that is received involuntarily or required under Federal, State, or local laws.

FFY stands for Federal fiscal year.

Medical care or treatment means health care furnished by or under the direction of a licensed physician that can involve diagnosing, treating, or preventing disease and other damage to the mind and body. It may involve the use of pharmaceuticals, diet, exercise, surgical intervention, and technical procedures.

Nonexcepted medical care means medical care (other than excepted medical care) that is sought by or for a beneficiary who has elected religious nonmedical health care institution services.

Religious nonmedical care or religious method of healing means health care furnished under established religious tenets that prohibit conventional or unconventional medical care for the treatment of a beneficiary, and the sole reliance on these religious tenets to fulfill a beneficiary's total health care needs.

RNHCI stands for ''religious nonmedical health care institution,'' as defined in section 1861(ss)(1) of the Act.

Religious nonmedical nursing personnel means individuals who are grounded in the religious beliefs of the RNHCI, trained and experienced in the principles of nonmedical care, and formally recognized as competent in the administration of care within their religious nonmedical health care group.

§ 403.720 Conditions for coverage.

Medicare covers services furnished in an RNHCI if the following conditions are met:

(a) The provider meets the definition of an RNHCI as defined in section 1861(ss)(1) of the Act. That is, it is an institution that:

(1) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxes under section 501(a).

(2) Is lawfully operated under all applicable Federal, State, and local laws and regulations.

(3) Furnishes only nonmedical nursing items and services to beneficiaries who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs.

(4) Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients.

(5) Furnishes nonmedical items and services to inpatients on a 24-hour basis.

(6) Does not furnish, on the basis of religious beliefs, through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients.

(7) Is not owned by, is not under common ownership with, or does not have an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment

or services or with an individual who has an ownership interest of 5 percent or more in, a provider of medical treatment or services. (Permissible affiliations are described at § 403.738(c).)

(8) Has in effect a utilization review plan that sets forth the following:

(i) Provides for review of the admissions to the institution, the duration of stays, and the need for continuous extended duration of stays in the institution, and the items and services furnished by the institution.

(ii) Requires that reviews be made by an appropriate committee of the institution that included the individuals responsible for overall administration and for supervision of nursing personnel at the institution.

(iii) Provides that records be maintained of the meetings, decisions, and actions of the review committee.

(iv) Meets other requirements as the Secretary finds necessary to establish an effective utilization review plan.

(9) Provides information CMS may require to implement section 1821 of the Act, including information relating to quality of care and coverage decisions.

(10) Meets other requirements CMS finds necessary in the interest of the health and safety of the patients who receive services in the institution. These requirements are the conditions of participation in this subpart.

(b) The provider meets the conditions of participation cited in §§ 403.730 through 403.746. (A provider may be deemed to meet conditions of participation in accordance with part 488 of this chapter.)

(c) The provider has a valid provider agreement as a hospital with CMS in accordance with part 489 of this chapter and for payment purposes is classified as an extended care hospital.

(d) The beneficiary has a condition that would make him or her eligible to receive services covered under Medicare Part A as an inpatient in a hospital or SNF.

(e) The beneficiary has a valid election as described in § 403.724 in effect for Medicare covered services furnished in an RNHCI.

§ 403.724 Valid election requirements.

(a) *General requirements.* An election statement must be made by the Medicare beneficiary or his or her legal representative.

(1) The election must be a written statement that must include the following statements:

(i) The beneficiary is conscientiously opposed to acceptance of nonexcepted medical treatment.

(ii) The beneficiary acknowledges that the acceptance of nonexcepted medical treatment is inconsistent with his or her sincere religious beliefs.

(iii) The beneficiary acknowledges that the receipt of nonexcepted medical treatment constitutes a revocation of the election and may limit further receipt of services in an RNHCI.

(iv) The beneficiary acknowledges that the election may be revoked by submitting a written statement to CMS.

(v) The beneficiary acknowledges that revocation of the election will not prevent or delay access to medical services available under Medicare Part A in facilities other than RNHCIs.

(2) The election must be signed and dated by the beneficiary or his or her legal representative.

(3) The election must be notarized.

(4) The RNHCI must keep a copy of the election statement on file and submit the original to CMS with any information obtained regarding prior elections or revocations.

(5) The election becomes effective on the date it is signed.

(6) The election remains in effect until revoked.

(b) *Revocation of election.* (1) A beneficiary's election is revoked by one of the following:

(i) The beneficiary receives nonexcepted medical treatment for which Medicare payment is requested.

(ii) The beneficiary voluntarily revokes the election and notifies CMS in writing.

(2) The receipt of excepted medical treatment as defined in § 403.702 does not revoke the election made by a beneficiary.

(c) *Limitation on subsequent elections.* (1) If a beneficiary's election has been made and revoked twice, the following

limitations on subsequent elections apply:

(i) The third election is not effective until 1 year after the date of the most recent revocation.

(ii) Any succeeding elections are not effective until 5 years after the date of the most recent revocation.

(2) CMS will not accept as the basis for payment of any claim any elections executed on or after January 1 of the calendar year in which the sunset provision described in § 403.756 becomes effective.

§ 403.730 Condition of participation: Patient rights.

An RNHCI must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* The RNHCI must do the following:

(1) Inform each patient of his or her rights in advance of furnishing patient care.

(2) Have a process for prompt resolution of grievances, including a specific person within the facility whom a patient may contact to file a grievance. In addition, the facility must provide patients with information about the facility's process as well as with contact information for appropriate State and Federal resources.

(b) *Standard: Exercise of rights.* The patient has the right to:

(1) Be informed of his or her rights and to participate in the development and implementation of his or her plan of care.

(2) Make decisions regarding his or her care, including transfer and discharge from the RNHCI. (See § 403.736 for discharge and transfer requirements.)

(3) Formulate advance directives and expect staff who furnish care in the RNHCI to comply with those directives, in accordance with part 489, subpart I of this chapter. For purposes of conforming with the requirement in § 489.102 that there be documentation in the patient's medical records concerning advanced directives, the patient care records of a beneficiary in an RNHCI are equivalent to medical records held by other providers.

(c) *Standard: Privacy and safety.* The patient has the right to the following:

(1) Personal privacy.

(2) Care in a safe setting.

(3) Freedom from verbal, psychological, and physical abuse, and misappropriation of property.

(4) Freedom from the use of restraints.

(5) Freedom from involuntary seclusion.

(d) *Standard: Confidentiality of patient records.* For any patient care records or election information it maintains on patients, the RNHCI must establish procedures to do the following:

(1) Safeguard the privacy of any information that identifies a particular patient. Information from, or copies of, records may be released only to authorized individuals, and the RNHCI must ensure that unauthorized individuals cannot gain access to or alter patient records. Original patient care records must be released only in accordance with Federal or State laws, court orders, or subpoenas.

(2) Maintain the records and information in an accurate and timely manner.

(3) Ensure timely access by patients to the records and other information that pertains to that patient.

(4) Abide by all Federal and State laws regarding confidentiality and disclosure for patient care records and election information.

§ 403.732 Condition of participation: Quality assessment and performance improvement.

The RNHCI must develop, implement, and maintain a quality assessment and performance improvement program.

(a) *Standard: Program scope.* (1) The quality assessment and performance improvement program must include, but is not limited to, measures to evaluate:

(i) Access to care.

(ii) Patient satisfaction.

(iii) Staff performance.

(iv) Complaints and grievances.

(v) Discharge planning activities.

(vi) Safety issues, including physical environment.

(2) In each of the areas listed in paragraph (a)(1) of this section, and any other areas the RNHCI includes, the RNHCI must do the following:

(i) Define quality assessment and performance improvement measures.

(ii) Describe and outline quality assessment and performance improvement activities appropriate for the services furnished by or in the RNHCI.

(iii) Measure, analyze, and track performance that reflect care and RNHCI processes.

(iv) Inform all patients, in writing, of the scope and responsibilities of the quality assessment and performance improvement program.

(3) The RNHCI must set priorities for performance improvement, considering the prevalence of and severity of identified problems.

(4) The RNHCI must act to make performance improvements and must track performance to assure that improvements are sustained.

(b) *Standard: Program responsibilities.* (1) The governing body, administration, and staff are responsible for ensuring that the quality assessment and performance improvement program addresses identified priorities in the RNHCI and are responsible for the development, implementation, maintenance, and performance improvement of assessment actions.

(2) The RNHCI must include all programs, departments, functions, and contracted services when developing, implementing, maintaining, and evaluating the program of quality assessment and performance improvement.

§ 403.734 Condition of participation: Food services.

The RNHCI must have an organized food service that is directed and adequately staffed by qualified personnel.

(a) *Standard: Sanitary conditions.* The RNHCI must furnish food to the patient that is obtained, stored, prepared, distributed, and served under sanitary conditions.

(b) *Standard: Meals.* The RNHCI must serve meals that furnish each patient with adequate nourishment in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. The RNHCI must do the following:

(1) Furnish food that is palatable, attractive, and at the proper temperature and consistency.

(2) Offer substitutes of similar nourishment to patients who refuse food served or desire alternative choices.

(3) Furnish meals at regular times comparable to normal mealtimes in the community. There must be no more than 14 hours between a substantial evening meal and breakfast the following day.

(4) The RNHCI must offer snacks at bedtime.

§ 403.736 Condition of participation: Discharge planning.

The RNHCI must have in effect a discharge planning process that applies to all patients. The process must assure that appropriate post-institution services are obtained for each patient, as necessary.

(a) *Standard: Discharge planning evaluation.* (1) The RNHCI must assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no planning and for any other patient upon his or her request or at the request of his or her legal representative. This discharge planning evaluation must be initiated at admission and must include the following:

(i) An assessment of the possibility of a patient needing post-RNHCI services and of the availability of those services.

(ii) An assessment of the probability of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the RNHCI.

(2) The staff must complete the assessment on a timely basis so that arrangements for post-RNHCI care are made before discharge and so that unnecessary delays in discharge are avoided.

(3) The discharge planning evaluation must be included in the patient's care record for use in establishing an appropriate discharge plan. Staff must discuss the results of the discharge planning evaluation with the patient or a legal representative acting on his or her behalf.

(b) *Standard: Discharge plan.* (1) If the discharge planning evaluation indicates a need for a discharge plan, qualified and experienced personnel must

develop or supervise the development of the plan.

(2) In the absence of a finding by the RNHCI that the beneficiary needs a discharge plan, the beneficiary or his or her legal representative may request a discharge plan. In this case, the RNHCI must develop a discharge plan for the beneficiary.

(3) The RNHCI must arrange for the initial implementation of the beneficiary's discharge plan.

(4) If there are factors that may affect continuing care needs or the appropriateness of the discharge plan, the RNHCI must reevaluate the beneficiary's discharge plan.

(5) The RNHCI must inform the beneficiary or legal representative about the beneficiary's post-RNHCI care requirements.

(6) The discharge plan must inform the beneficiary or his or her legal representative about the freedom to choose among providers of care when a variety of providers is available that are willing to respect the discharge preferences of the beneficiary or legal representative.

(c) *Standard: Transfer or referral.* The RNHCI must transfer or refer patients in a timely manner to another facility (including a medical facility if requested by the beneficiary, or his or her legal representative) in accordance with § 403.730(b)(2).

(d) *Standard: Reassessment.* The RNHCI must reassess its discharge planning process on an ongoing basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

[64 FR 67047, Nov. 30, 1999, as amended at 68 FR 66720, Nov. 28, 2003]

§ 403.738 Condition of participation: Administration.

An RNHCI must have written policies regarding its organization, services, and administration.

(a) *Standard: Compliance with Federal, State, and local laws.* The RNHCI must operate in compliance with all applicable Federal, State, and local laws, regulations, and codes including, but not limited to, those pertaining to the following:

(1) Protection against discrimination on the basis of race, color, national origin, age, or handicap (45 CFR parts 80, 84, and 91).

(2) Protection of human research subjects (45 CFR part 46).

(3) Application of all safeguards to protect against the possibility of fraud and abuse (42 CFR part 455).

(4) Privacy of individually identifiable health information (45 CFR part 164).

(b) *Standard: Governing body.* (1) The RNHCI must have a governing body, or a person designated to function as a governing body, that is legally responsible for establishing and implementing all policies regarding the RNHCI's management and operation.

(2) The governing body must appoint the administrator responsible for the management of the RNHCI.

(c) *Standard: Affiliations and disclosure.* (1) An affiliation is permissible if it is between one of the following:

(i) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of an RNHCI and a provider of medical treatment or services.

(ii) An individual who is a director, trustee, officer, employee, or staff member of an RNHCI and another individual, with whom he or she has a family relationship, who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(iii) The RNHCI and an individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and RNHCIs.

(2) The RNHCI complies with the disclosure requirements of §§ 420.206 and 455.104 of this chapter.

(3) The RNHCI furnishes written notice, including the identity of each new individual or company, to CMS at the time of a change, if a change occurs in any of the following:

(i) Persons with an ownership or control interest, as defined in §§ 420.201 and 455.101 of this chapter.

(ii) The officers, directors, agents, or managing employees.

(iii) The religious entity, corporation, association, or other company responsible for the management of the RNHCI.

(iv) The RNHCI's administrator or director of nonmedical nursing services.

[64 FR 67047, Nov. 30, 1999, as amended at 68 FR 66720, Nov. 28, 2003]

§ 403.740 Condition of participation: Staffing.

The RNHCI must be staffed with qualified experienced personnel who are present in sufficient numbers to meet the needs of the patients.

(a) *Standard: Personnel qualifications.* The RNHCI must ensure that staff who supervise or furnish services to patients are qualified to do so and that staff allowed to practice without direct supervision have specific training to furnish these services.

(b) *Standard: Education, training, and performance evaluation.* (1) The RNHCI must ensure that staff (including contractors and other individuals working under arrangement) have the necessary education and training concerning their duties so that they can furnish services competently. This education includes, but is not limited to, training related to the individual job description, performance expectations, applicable organizational policies and procedures, and safety responsibilities.

(2) Staff must demonstrate, in practice, the skills and techniques necessary to perform their duties and responsibilities.

(3) The RNHCI must evaluate the performance of staff and implement measures for improvement.

§ 403.742 Condition of participation: Physical environment.

A RNHCI must be designed, constructed, and maintained to ensure the safety of the patients, staff, and the public.

(a) *Standard: Buildings.* The physical plant and the overall environment must be maintained in a manner that ensures the safety and well-being of the patients. The RNHCI must have the following:

(1) Emergency power for emergency lights, for fire detection and alarm systems, and for fire extinguishing systems.

(2) Procedures for the proper storage and disposal of trash.

(3) Proper ventilation and temperature control and appropriate lighting levels to ensure a safe and secure environment.

(4) A written disaster plan to address loss of power, water, sewage, and other emergencies.

(5) Facilities for emergency gas and water supply.

(6) An effective pest control program.

(7) A preventive maintenance program to maintain essential mechanical, electrical, and fire protection equipment operating in an efficient and safe manner.

(8) A working call system for patients to summon aid or assistance.

(b) *Standard: Patient rooms.* Patient rooms must be designed and equipped for adequate care, comfort, and privacy of the patient.

(1) Patient rooms must meet the following conditions:

(i) Accommodate no more than four patients.

(ii) Measure at least 80 square feet per patient in multiple patient rooms and at least 100 square feet in single patient rooms.

(iii) Have direct access to an exit corridor.

(iv) Be designed or equipped to assure full visual privacy for each patient.

(v) Have at least one window to the outside.

(vi) Have a floor at or above grade level.

(2) The RNHCI must furnish each patient with the following:

(i) A separate bed of proper size and height for the convenience of the patient.

(ii) A clean, comfortable mattress.

(iii) Bedding appropriate to the weather and climate.

(iv) Functional furniture appropriate to the patient's needs and individual closet space with clothes racks and shelves accessible to the patient.

(3) CMS may permit variances in requirements specified in paragraphs (b)(1)(i) and (ii) of this section relating to rooms on an individual basis when the RNHCI adequately demonstrates in writing that the variances meet the following:

(i) Are in accordance with the special needs of the patients.

(ii) Will not adversely affect patients' health and safety.

§ 403.744 Condition of participation: Life safety from fire.

(a) *General.* An RNHCI must meet the following conditions:

(1) Except as otherwise provided in this section—

(i) The RNHCI must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted Life Safety Code does not apply to an RNHCI.

(2)—(3) [Reserved]

(4) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, the RNHCI may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(b) *Exceptions.* (1) If application of the Life Safety Code required under paragraph (a)(1) of this section would result in unreasonable hardship upon the RNHCI, CMS may waive specific provisions of the Life Safety Code, but only if the waiver does not adversely affect the health and safety of patients.

(2) If CMS finds that the fire and safety code imposed by State law adequately protects patients in the institution, the provisions of the Life Safety Code required in paragraph (a)(1) of this section do not apply in that State.

(c) *Phase-in period.* Beginning March 13, 2006, an RNHCI must be in compliance with Chapter 19.2.9, Emergency Lighting. Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to RNHCIs.

[64 FR 67047, Nov. 30, 1999, as amended at 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 69 FR 49240, Aug. 11, 2004; 70 FR 15237, Mar. 25, 2005]

§ 403.746 Condition of participation: Utilization review.

The RNHCI must have in effect a written utilization review plan to assess the necessity of services furnished. The plan must provide that records be maintained of all meetings, decisions, and actions by the utilization review committee.

(a) *Standard: Utilization review plan.* The utilization review plan must contain written procedures for evaluating the following:

(1) Admissions.

(2) Duration of care.

(3) Continuing care of an extended duration.

(4) Items and services furnished.

(b) *Standard: Utilization review committee.* The committee is responsible for evaluating each admission and ensuring that the admission is necessary and appropriate. The utilization review plan must be carried out by the utilization review committee, consisting of the governing body, administrator or other individual responsible for the overall administration of the RNHCI, the supervisor of nursing staff, and other staff as appropriate.

(c) *Standard: Utilization review committee role in RNHCI home services.* In addition to the requirements in paragraphs (a) and (b) of this section, the utilization review committee is responsible for:

(1) The admission, and at least every 30 days, the continued care review of each patient in the RHNCI home services program.

(2) Oversight and monitoring of the home services program, including the purchase and utilization of designated durable medical equipment items for beneficiaries in the program.

[64 FR 67047, Nov. 30, 1999, as amended at 69 FR 66419, Nov. 15, 2004]

§ 403.750 Estimate of expenditures and adjustments.

(a) *Estimates.* CMS estimates the level of expenditures for services provided under this subpart before the start of each FFY beginning with FFY 2000.

(b) *Adjustments to payments.* When the level of estimated expenditures is projected to exceed the FFY trigger level as described in paragraph (d) of this section, for the year of the projection, payments to RNHCIs will be reduced by a proportional percentage to prevent estimated expenditures from exceeding the trigger level. In addition to reducing payments proportionally, CMS may impose alternative adjustments.

(c) *Notification of adjustments.* CMS notifies participating RNHCIs before the start of the FFY of the type and level of expenditure reductions to be made and when these adjustments will apply.

(d) *Calculation of trigger level.* The trigger level for FFY 1998 is $20,000,000. For subsequent FFYs, the trigger level is the unadjusted trigger level increased or decreased by the carry forward as described in § 403.754(b). The unadjusted trigger level is the base year amount (the unadjusted trigger level dollar amount for the prior FFY) increased by the average consumer price index (the single numerical value published monthly by the Bureau of Labor Statistics that presents the relationship in United States urban areas for the current cost of goods and services compared to a base year, to represent the change in spending power) for the 12-month period ending on July 31 preceding the beginning of the FFY.

§ 403.752 Payment provisions.

(a) *Payment to RNHCIs.* Payment for services may be made to an RNHCI that meets the conditions for coverage described in § 403.720 and the conditions of participation described in §§ 403.730 through 403.746. Payment is made in accordance with § 413.40 of this chapter to an RNHCI meeting these conditions.

(b) *Review of estimates and adjustments.* There is no administrative or judicial review of the level of estimated expenditures or the adjustments in payments described in §§ 403.750(a) and (b).

(c) *Effect on beneficiary liability.* When payments are reduced in accordance with § 403.750(b), the RNHCI may bill the beneficiary the amount of the Medicare reduction attributable to his or her covered services.

(d) *Notification of beneficiary liability.* (1) The RNHCI must notify the beneficiary in writing at the time of admission of any proposed or current proportional Medicare adjustment. A beneficiary currently receiving care in the RNHCI must be notified in writing at least 30 days before the Medicare reduction is to take effect. The notification must inform the beneficiary that the RNHCI can bill him or her for the proportional Medicare adjustment.

(2) The RNHCI must, at time of billing, provide the beneficiary with his or her liability for payment, based on a

calculation of the Medicare reduction pertaining to the beneficiary's covered services permitted by § 403.750(b).

§ 403.754 Monitoring expenditure level.

(a) *Tracking expenditures*. Starting in FFY 1999 CMS begins monitoring Medicare payments to RNHCIs.

(b) *Carry forward*. The difference between the trigger level and Medicare expenditures for a FFY results in a carry forward that either increases or decreases the unadjusted trigger level described in § 403.750(d). In no case may the carry forward exceed $50,000,000 for an FFY.

§ 403.756 Sunset provision.

(a) *Effective date*. Beginning with FFY 2002, if the level of estimated expenditures for all RNHCIs exceeds the trigger level for 3 consecutive FFYs, CMS will not accept as the basis for payment of any claim any election executed on or after January 1 of the following calendar year.

(b) *Notice of activation*. A notice in the FEDERAL REGISTER will be published at least 60 days before January 1 of the calendar year that the sunset provision becomes effective.

(c) *Effects of sunset provision*. Only those beneficiaries who have a valid election in effect before January 1 of the year in which the sunset provision becomes effective will be able to claim Medicare payment for care in an RNHCI, and only for RNCHI services furnished during that election.

§ 403.764 Basis and purpose of religious nonmedical health care institutions providing home service.

(a) *Basis*. This subpart implements sections 1821, 1861, 1861(e), 1861(m), 1861(y), 1861(ss) and 1861(aaa), 1869 and 1878 of the Act regarding Medicare payment for items and services provided in the home setting furnished to eligible beneficiaries by religious nonmedical health care institutions (RNHCIs).

(b) *Purpose*. The home benefit provides for limited durable medical equipment (DME) items and RNHCI services in the home setting that are fiscally limited to $700,000 per calendar year, with an expiration date of December 31, 2006, or the date on which the 2006 spending limit is reached.

[69 FR 66419, Nov. 15, 2004]

§ 403.766 Requirements for coverage and payment of RNHCI home services.

(a) Medicare Part A pays for RNHCI home services if the RNHCI provider does the following:

(1) Submit a notice of intent to CMS to exercise the option of providing home service.

(2) Provide RNHCI services to eligible beneficiaries,

(3) Arrange with suppliers to furnish appropriate DME items as required to meet documented eligible beneficiary needs.

(4) Arrange for RNHCI nurse home visits to eligible beneficiaries.

(5) Have a utilization committee that assumes the additional responsibility for the oversight and monitoring of the items and RNHCI nursing services provided under the home benefit.

(6) Meet all applicable requirements set forth in subpart G of this part.

(b) To be an eligible beneficiary to RNHCI home services the beneficiary must:

(1) Have an effective election in place.

(2) Be confined to the home, as specified in § 409.42(a) of this chapter.

(3) Have a condition that makes him or her eligible to receive services covered under Medicare home health.

(4) Receive home services and DME items from a RNHCI.

(5) Be responsible for deductible and coinsurance for DME, as specified in § 409.50 of this chapter.

[69 FR 66419, Nov. 15, 2004, as amended at 70 FR 16721, Apr. 1, 2005]

§ 403.768 Excluded services.

In addition to items and services excluded in § 409.49 of this chapter, items and services are also excluded if they are provided by:

(a) A HHA that is not a RNHCI.

(b) A supplier who is not providing RNHCI designated items under arrangement with a RNHCI.

(c) A nurse who is not providing RNHCI home nursing services under arrangement with a RNHCI.

[69 FR 66419, Nov. 15, 2004]

§ 403.770 Payments for home services.

(a) The RNHCI nursing visits are paid at the modified low utilization payment adjusted (LUPA) rate used under the home health prospective payment system at § 484.230 of this chapter.

(b) Appropriate DME items are paid as priced by Medicare, minus the deductible and coinsurance liability of the beneficiary.

[69 FR 66419, Nov. 15, 2004]

Subpart H—Medicare Prescription Drug Discount Card and Transitional Assistance Program

SOURCE: 68 FR 69915, Dec. 15, 2003, unless otherwise noted.

§ 403.800 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–31 of the Social Security Act (the Act).

(b) *Scope.* This subpart sets forth the standards and procedures CMS uses to implement the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

§ 403.802 Definitions.

For purposes of this subpart, the following definitions apply:

Affiliated organization means an organization that is a legally separate entity from the endorsed drug card sponsor and meets one of the following conditions:

(1) The organization and the endorsed drug card sponsor are under common control. Common control exists if another entity has the power, directly or indirectly, to significantly influence or direct the actions or policies of the organization and the endorsed drug card sponsor.

(2) The organization is under the control of the endorsed drug card sponsor or the organization controls the endorsed drug card sponsor. Control exists if an entity has the power, directly or indirectly, to significantly influence or direct the actions or policies of another entity.

(3) The organization possesses an ownership or equity interest of 5 percent or more in the endorsed drug card sponsor on both the date on which the endorsed drug card sponsor markets the organization's Part D plan, and the date on which the endorsed drug card sponsor signed its endorsement contract with CMS.

Annual coordinated election period means the period beginning on November 15, 2004 and ending on December 31, 2004, during which a discount card enrollee may elect to disenroll from their current endorsed discount card program and elect enrollment in another endorsed discount card program effective January 1, 2005.

Applicant means the non-governmental, single legal organization or entity doing business in the United States that is applying for Medicare endorsement of its prescription drug discount card program, as described in its application, to be operated by itself or in coordination with subcontractors.

Application means the document submitted to CMS by an applicant that seeks to demonstrate the applicant's compliance with the requirements specified in this subpart in order to obtain Medicare endorsement of the applicant's prescription drug discount card program.

Authorized representative means a person with legal authority to act on behalf of an individual in making decisions related to the individual's health care or the individual's enrollment in, disenrollment from, and access to negotiated prices and transitional assistance under the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

Covered discount card drug means any of the following: a drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act; a biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act; insulin described in section 1927(k)(2)(C) of the Act; the following medical supplies associated with the injection of insulin: syringes, needles, alcohol swabs, and gauze; a vaccine licensed under section 351 of the Public

Health Service Act; or any use of a covered discount card drug for a medically accepted indication (as defined in section 1927(k)(6) of the Act). The definition of covered discount card drug excludes the following: agents when used for anorexia, weight loss, or weight gain; agents when used to promote fertility; agents when used for cosmetic purposes or hair growth; agents when used for the symptomatic relief of cough and colds; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; nonprescription drugs; outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; barbiturates; and benzodiazepines.

Discount card enrollee or enrollee or card enrollee means an individual described in § 403.810(a) who elects to enroll in a Medicare-endorsed prescription drug discount card program.

Effective date means the date on which an enrollment or disenrollment transaction becomes effective.

Enrollment period means the period beginning on the initial enrollment date and ending on December 31, 2005.

Exclusive card program means an endorsed discount card program that is offered by an exclusive card sponsor.

Exclusive card sponsor means an endorsed sponsor that also operates one or more Medicare managed care plans and limits enrollment in its endorsed discount card program to individuals described in § 403.810(a) who are enrollees in one of the Medicare managed care plans it offers.

Family size means one for individuals who are single, and two for individuals who are married.

Federal Employee's Health Benefits Program plan means a plan under chapter 89 of title 5 of the United States Code including the Retired Federal Employee's Health Benefits Program.

Formulary means the list of specific drugs from among covered discount card drugs for which an endorsed sponsor offers negotiated prices to Medicare beneficiaries enrolled in its Medicare-endorsed prescription drug discount card program.

Group enrollment means simultaneous enrollment of all or some of the individuals described in sectioin 403.810(a) who are members of a Medicare managed care plan into the exclusive card program offered by the Medicare managed care organization.

HIPAA means the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d and section 264 of Public Law 104–191.

Income means the components of an individual's adjusted gross income (AGI), as defined under 26 U.S.C. section 62, and, to the extent not included in the components of AGI, retirement and disability benefits, or, if he or she is married, the sum of such income for the individual and his or her spouse.

Initial enrollment date means the date established by the Secretary on which endorsed sponsors may begin accepting beneficiaries' standard enrollment forms.

Initial enrollment year means the period beginning on the initial enrollment date and ending on December 31, 2004.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility, as defined in section 1819(a) of the Act, or nursing facility, as defined in section 1919(a) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Medicare cost plan means an organization that offers enrollment under a reasonable cost reimbursement contract under section 1876(h) of the Act.

Medicare managed care organization means a Part C organization offering a Part C plan described in section 1851(a)(2)(A) of the Act or a Medicare cost plan.

Medicare managed care plan means a plan described in section 1851(a)(2)(A) of the Act offered by a Part C organization or a Medicare cost plan.

Medicare Prescription Drug Discount Card and Transitional Assistance Program or Medicare Drug Discount Card Program means the program established under section 1860D–31 of the Act.

Medicare-endorsed prescription drug discount card program, or endorsed program, or endorsed discount card program means any prescription drug discount card program that has received Medicare endorsement and whose endorsed sponsor has entered into a contract with CMS.

Medicare-endorsed prescription drug discount card sponsor, or endorsed sponsor, or endorsed discount card sponsor means any applicant that has received endorsement from Medicare and entered into a contract with CMS to operate an approved Medicare-endorsed discount card program.

Negotiated price means the discounted price for a covered discount card drug offered by an endorsed sponsor, including any dispensing fee, which takes into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations.

Network pharmacy means a licensed pharmacy that is not a mail order pharmacy and that is under contract with an endorsed sponsor to provide negotiated prices to its card enrollees and accept transitional assistance as payment for covered discount card drugs provided to its transitional assistance enrollees.

New Medicare managed care organization means an entity applying for approval to enter into a new contract with CMS to offer a new, coordinated care plan or plans as described in section 1851(a)(2)(A) of the Act under Medicare Part C and an exclusive card program under the Medicare Drug Discount Card Program.

Over-the-counter drug means a nonprescription drug.

Part C organization means an organization offering a Part C plan.

Part C plan means a plan described in section 1859(b)(1) of the Act.

Part D plan has the meaning given the term at § 423.4.

Pharmacy network means the group of network pharmacies under contract with an endorsed sponsor.

Poverty line means the income level defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), including any revision required by such section, applicable to the family size involved.

Rural means a five-digit zip code in which the population density is less than 1000 persons per square mile.

Second enrollment year means the period beginning on January 1, 2005 and ending on December 31, 2005.

Solicitation means the application materials identified in the notice CMS publishes in the FEDERAL REGISTER announcing its intention to accept and consider applications from applicants seeking Medicare endorsement for their prescription drug discount card programs.

Special election period means the period beginning the day after the effective date of an individual's disenrollment from an endorsed discount card program for one of the reasons listed in § 403.811(b)(2). The length of any given election period will be specified by CMS in a form and manner that supports the goals of the Medicare Drug Discount Card Program.

Special endorsed sponsor means an endorsed sponsor who has received special endorsement by CMS.

Special endorsement means an endorsement granted under § 403.816 or § 403.817.

Standard enrollment form means an enrollment form or other approved process for enrolling individuals into an endorsed program that incorporates the standard elements provided by CMS.

Subcontractor means an organization or entity doing business in the United States with which an applicant or endorsed sponsor enters into a contract or other legal arrangement in connection with the operation of a prescription drug discount card program.

Suburban means a five-digit zip code in which the population density is between 1000 and 3000 persons per square mile.

Transition period means the period beginning on January 1, 2006 and ending, for individuals enrolled for coverage under Part D, on the effective date of the individual's coverage, and for individuals not so enrolled, on the last day

of the initial Part D open enrollment period.

Transitional assistance means a subsidy that transitional assistance enrollees may apply toward the cost of covered discount card drugs in the manner described in § 403.808(d).

Transitional assistance effective date means the date on which a transitional assistance enrollee can access transitional assistance.

Transitional assistance enrollee means an individual described in § 403.810(b) who has applied for and been determined eligible for transitional assistance and has enrolled in a discount card program.

Urban means a five-digit zip code in which the population density is greater than 3000 persons per square mile.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52022, Sept. 1, 2005]

§ 403.804 General rules for solicitation, application and Medicare endorsement period.

(a) *Application.* (1) Except as provided in paragraph (a)(2) of this section, an applicant must submit an application to CMS by the deadline announced in the solicitation to be eligible for Medicare endorsement of its prescription drug discount card program. The applicant must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

(2) A new Medicare managed care organization may simultaneously apply to offer a new Part C plan or plans and an exclusive card program after the deadline announced in the solicitation. New Medicare managed care organizations seeking endorsement of their prescription drug discount card programs must submit an application to CMS at the time that they submit their Part C applications. New Medicare managed care organizations will be eligible for endorsement provided CMS approves their Part C application, the new Medicare managed care organizations demonstrate to CMS that they meet the criteria under paragraph (b) of this section, and the new Medicare managed care organizations demonstrate that they will meet the requirements of paragraph (e)(2) of this section.

(b) *Eligibility to receive endorsement.* Except as specified in §§ 403.814, 403.816 and 403.817, an applicant will be eligible for endorsement if its application demonstrates to CMS's satisfaction that the applicant meets the requirements of § 403.806(a) and § 403.806(b)(1) and that it would operate its endorsed program in a manner consistent with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m). An applicant that submits a complete application that meets all of the requirements of this subpart will be eligible to enter into a contract with CMS to operate a Medicare-endorsed prescription drug discount card program. Following the receipt of its Medicare endorsement, an endorsed sponsor must comply with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m) through the end of the transition period.

(c) *Ability to subcontract with other organizations and entities.* (1) An applicant for endorsement may demonstrate that it meets the requirements of this subpart by combining with subcontractors.

(2) Any subcontracts must be in final form satisfactory to CMS, signed by all applicable parties, and filed with CMS before an endorsed sponsor will be permitted to engage in any enrollment or information and outreach.

(3) Once endorsed, an endorsed sponsor must ensure that its subcontractors comply with all applicable requirements of this subpart.

(d) *Period of endorsement.* An applicant eligible to receive endorsement will be required to sign a contract with CMS agreeing to operate its approved Medicare-endorsed prescription drug discount card program(s) until the end of the transition period.

(e)(1) Except as provided in paragraph (e)(2) of this section, we expect an endorsed sponsor to be ready by June 8, 2004, to initiate enrollment and fully operate its endorsed program in compliance with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m).

(2) A new Medicare managed care organization must be ready to initiate enrollment and fully operate its exclusive card program in compliance with the requirements of §§ 403.806(b)(2) and

(b)(3) through § 403.806(m) upon approval of its Part C application and application for Medicare endorsement of its prescription drug discount card program.

§ 403.806 Sponsor requirements for eligibility for endorsement.

Except as specified in § 403.814, § 403.816, and § 403.817, an endorsed sponsor must meet the following requirements:

(a) *Applicant experience.* (1) An applicant must be a non-governmental, single legal entity doing business in the United States.

(2) An applicant must have 3 years of private sector experience in the United States in pharmacy benefit management, which is defined to mean—

(i) Adjudicating and processing claims for drugs at the point of sale;

(ii) Negotiating with prescription drug manufacturers and others for discounts, rebates, and/or other price concessions on prescription drugs; and

(iii) Administering and tracking individuals' subsidies or benefits in real time.

(3) A single legal entity which is either the applicant or a subcontractor must, at the time of application for Medicare endorsement, operate a pharmacy benefit program, a prescription drug discount card program, a low-income drug assistance program, or a similar program that serves at least 1 million covered lives.

(b) *Financial stability and business integrity.* (1) An applicant must demonstrate a satisfactory record of the financial stability and business integrity of itself, any subcontractors on whom the applicant relies to satisfy the 3 years experience requirement in paragraph (a)(2) of this section and the 1 million covered lives requirement in paragraph (a)(3) of this section, and any subcontractors engaged by the applicant to perform the following activities: develop the pharmacy network; negotiate with manufacturers or pharmacies for rebates, discounts, or other price concessions; handle eligibility for or enrollment in the endorsed sponsor's endorsed discount card program and/or transitional assistance; and administer transitional assistance.

(2) An endorsed sponsor and any subcontractors described in paragraph (b)(1) of this section must maintain a satisfactory record of financial stability and business integrity during the term of the endorsed program.

(3) Medicare endorsement of a discount card program shall not be construed to express or imply any opinion that an endorsed sponsor or any subcontractor of an endorsed sponsor is in compliance with or not liable under the False Claims Act, anti-kickback statute (section 1128B(b) of the Act), or other legal authorities for any improper billing, claims submission, or related conduct.

(c) *Compliance with applicable law.* An endorsed sponsor must comply with all applicable Federal and State laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).

(d) *Prescription drug offering.* An endorsed sponsor must comply with the following discount, rebate, and formulary requirements:

(1) Offer all of its discount card enrollees negotiated prices on covered discount card drugs, which may be limited to those covered discount card drugs included on the endorsed sponsor's formulary.

(2) If the endorsed sponsor uses a formulary, offer a negotiated price on at least one covered discount card drug in each of the lowest level categories for each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS. A specific covered discount card drug may not be used to fulfill this requirement for more than one category.

(3) Offer a negotiated price on a generic drug in at least 55 percent of the lowest level categories in each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS.

(4) In setting negotiated prices under this section, an endorsed sponsor may vary its prices and the drugs included on the formulary by pharmacy contract and enrollee characteristics, such as transitional assistance eligibility status.

(5) Synchronize changes in the list of, and negotiated prices for, covered discount card drugs included in the endorsed sponsor's formulary with formulary and negotiated prices published on a price comparison Web site, as described in paragraph (i)(4)(v) of this section.

(6) Obtain rebates, discounts, or other price concessions from manufacturers on covered discount card drugs and pass a share of such concessions to enrollees through negotiated prices.

(7) Guarantee that network and mail order pharmacies provide the lower of the negotiated price or usual and customary price when a covered discount card drug for a negotiated price is available at the point of sale.

(8) Guarantee that a network pharmacy, at the point of sale, inform a discount card enrollee of any differential between the price of a prescribed drug (if it is a covered discount card drug) and the price of the lowest priced generic covered discount card drug that is therapeutically equivalent and bioequivalent and available at such pharmacy. Mail order pharmacies are to provide this information at the time of delivery of the drug.

(9) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), ensure that any increase in the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to the changes in the endorsed sponsor's cost structure, including material changes to any discounts, rebates, or other price concessions the endorsed sponsor receives from a pharmaceutical manufacturer or pharmacy.

(e) *Transitional assistance administration.* An endorsed sponsor must administer transitional assistance funds, including any roll-over funds as described in §403.808(f), for transitional assistance enrollees, through the following procedures:

(1) Establish accounting procedures to manage the transitional assistance funds for each transitional assistance enrollee.

(2) Ensure that transitional assistance funds are applicable to, and only to, all covered discount card drugs available at the endorsed sponsors' network and mail order pharmacies, regardless of formulary.

(3) Ensure that, at network and mail order pharmacies, transitional assistance funds are applied at the lower of negotiated price (if any) and the pharmacy's usual and customary price.

(4) Ensure that network pharmacies make available to the transitional assistance enrollee, electronically or by telephone, at the point-of-sale of covered discount card drugs, the amount of transitional assistance remaining available to the transitional assistance enrollee. Mail order pharmacies are to make this information available by telephone.

(5) Maintain a toll-free telephone number that discount card enrollees may use to determine their transitional assistance balances.

(6) Enforce coinsurance requirements described in §403.808(e) and ensure that the portion of the price paid through coinsurance is not deducted from the total transitional assistance funds available to the discount card enrollee.

(f) *Service area and pharmacy access.* An endorsed sponsor must meet the following requirements for its service area and its pharmacy network:

(1) The service area must cover one or more States.

(2) The endorsed sponsor's discount card program must be available to all eligible individuals residing in each State in the endorsed sponsor's service area and may not be offered to individuals residing outside of the United States.

(3) The endorsed sponsor must have a contracted pharmacy network, consisting of pharmacies other than mail-order pharmacies, sufficient to ensure that for beneficiaries residing in the endorsed sponsor's service area the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the endorsed program, live within 2 miles of a network pharmacy;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the endorsed program, live within 5 miles of a network pharmacy; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the endorsed program, live within 15 miles of a network pharmacy.

(4) The endorsed sponsor's pharmacy network may be supplemented by pharmacies offering home delivery via mail-order, provided the requirements of paragraph (f)(3) of this section are met.

(g) *Information and outreach and customer service.* (1) An endorsed sponsor must provide through the Internet and some other tangible medium (such as a mailing) to Medicare beneficiaries information and outreach materials describing its endorsed drug card program, including the following information—

(i) The enrollment fee;

(ii) Negotiated prices offered for covered discount card drugs;

(iii) If offered, discounts on over-the-counter drugs;

(iv) Any other products or services offered under the endorsement; and

(v) Any other information that CMS determines is necessary for a full description of the endorsed discount drug card program.

(2) An endorsed sponsor must include on a Web site the following:

(i) Information regarding when the Web site was last updated; and

(ii) A disclaimer that the information on the Web site may not be current.

(3) An endorsed sponsor must use the following forms which incorporate standard elements provided by CMS:

(i) An enrollment form (except as may be modified for an exclusive card sponsor as discussed in § 403.814(b)(5)(iii); and

(ii) An eligibility determination notice.

(4) An endorsed sponsor must provide to each enrollee a card that complies with National Council for Prescription Drug Programs standards.

(5) An endorsed sponsor must meet the following requirements for the review and approval of information and outreach materials:

(i) Comply with the Information and Outreach Guidelines published by CMS except as provided in paragraph (g)(5)(vi) of this section.

(ii) Except as provided in paragraph (g)(5)(iii) of this section, not distribute any information and outreach materials until or unless they are approved by CMS.

(iii) If CMS does not disapprove the initial submission of information and outreach materials within 30 days of receipt of these materials, the materials are deemed approved under paragraph (g)(5)(ii) of this section.

(iv) Information and outreach materials may discuss only products or services inside the scope of endorsement, as described in paragraph (h) of this section.

(v) Information and outreach materials include the same kinds of materials described in 42 CFR 422.80(b), as well as the enrollment form, eligibility determination form, and membership card described in paragraphs (g)(3) and (g)(4) of this section, Web site content, and information regarding discounts for over-the-counter drugs.

(vi) All materials related to products and services that are Part D plans must comply with the requirements specified in § 423.50 of this chapter.

(6) An endorsed sponsor must maintain a toll-free customer call center that is open during usual business hours and that provides customer telephone service, including to pharmacists, in accordance with standard business practices. The endorsed sponsor must inform enrollees that the toll-free telephone number provides information on the amount of remaining transitional assistance, in accordance with paragraph (e)(5) of this section.

(7) An endorsed sponsor must provide a system to reduce the likelihood of medical errors and adverse drug interactions and to improve medication use.

(h) *Products and services inside and outside the scope of the endorsement.* (1) An endorsed sponsor may provide, under the endorsement, only those products and services inside the scope of the endorsement, including conducting enrollment. An endorsed sponsor must ensure that discount card enrollees are not charged any additional fee (other than the enrollment fee allowed under § 403.811(c)) for products or services inside the scope of the endorsement.

(2) Products and services inside the scope of the endorsement are limited to—

(i) Products or services offered for no additional fee, other than the enrollment fee allowed under § 403.811(c), that are directly related to a covered discount card drug; or

(ii) A discounted price for an over-the-counter drug.

(i) *Reporting.* (1) An endorsed sponsor must report to CMS on a periodic basis information on the major features of the endorsed sponsor's programs that correspond to the qualifications for endorsement, including, but not limited to, information concerning—

(i) Savings from pharmacies and manufacturers obtained through rebates, discounts, and other price concessions;

(ii) Savings shared with discount card enrollees by manufacturer, by all retail pharmacies, by all mail order pharmacies, and by all brand name and all generic covered discount card drugs;

(iii) Dispensing fees;

(iv) Certified (by the chief financial officer) financial accounting records on transitional assistance used by the transitional assistance enrollees in each month;

(v) Participant utilization and spending statements;

(vi) Utilization and spending for selected drugs;

(vii) Performance on customer service metrics such as call center performance;

(viii) Grievance logs; and

(ix) Endorsed sponsor's compliance with the pharmacy network access standards.

(2) An endorsed sponsor must provide notice of, and the rationale for, negotiated price increases, except for increases during the week of November 15, 2004, due to reasons other than changes in average wholesale price (AWP).

(3) An endorsed sponsor must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

(4) Through a price comparison Web site, an endorsed sponsor must report the following information:

(i) Customer service hours;

(ii) Customer service contact information;

(iii) Endorsed program Web site address;

(iv) Annual enrollment fee; and

(v) Negotiated prices (including any applicable dispensing fee), for every covered discount card drug included in the discount card program's offering.

(5) CMS may require endorsed sponsors to submit, in standard terminology, descriptions of other discount card related services they provide, such as pharmacist services.

(j) *Grievance process.* An endorsed sponsor must establish and maintain a grievance process. This process must be designed to track and appropriately address in a timely manner enrollees' complaints about any aspect of their endorsed program for which the endorsed sponsor is responsible.

(k) *Eligibility, enrollment, and disenrollment.* (1) An endorsed sponsor must make preliminary eligibility determinations in accordance with § 403.810 and conduct enrollment and disenrollment in accordance with § 403.811.

(l) *Authorized representative.* An endorsed sponsor must treat an individual's authorized representative as the individual, if under applicable law, the authorized representative has the legal authority to act on behalf of the individual with respect to the action at issue.

(m) *Other.* An endorsed sponsor must meet the requirements of §§ 403.812, 403.813, and 403.822 of this subpart.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52023, Sept. 1, 2005]

§ 403.808 Use of transitional assistance funds.

(a) *Individuals determined eligible for transitional assistance in 2004.* Subject to paragraph (d) of this section, an individual who, in calendar year 2004, is determined eligible for transitional assistance under § 403.810(b) is entitled to the following:

(1) $600 in calendar year 2004; and

(2) $600 in calendar year 2005.

(b) *Individuals determined eligible for transitional assistance in 2005.* Subject to

paragraph (d) of this section, an individual who, in calendar year 2005, is determined eligible for transitional assistance under § 403.810(b) is entitled to one of the following amounts for calendar year 2005:

(1) If the complete application for the individual's transitional assistance eligibility is received on or after January 1, 2005 and before April 1, 2005, $600.

(2) If the complete application for the individual's transitional assistance eligibility is received on or after April 1, 2005 and before July 1, 2005, $450.

(3) If the complete application for the individual's transitional assistance eligibility is received on or after July 1, 2005 and before October 1, 2005, $300.

(4) If the complete application for the individual's transitional assistance eligibility is received on or after October 1, 2005 and on or before December 31, 2005, $150.

(c) *Payment of enrollment fee.* An individual found eligible for transitional assistance is entitled to have CMS pay the annual enrollment fee to the endorsed sponsor on his or her behalf.

(d) *Conditions on use of transitional assistance.* A transitional assistance enrollee may access the transitional assistance described in paragraphs (a) and (b) of this section only if the following conditions are met:

(1) Except as provided in § 403.814(b)(3)(v), the transitional assistance funds are applied toward the cost of a covered discount card drug obtained under the Medicare Prescription Drug Discount Card and Transitional Assistance Program;

(2) The individual pays a coinsurance amount in accordance with § 403.808(e);

(3) The individual purchases the covered discount card drug on or after the individual's transitional assistance effective date; and

(4) The individual is enrolled in the Medicare Prescription Drug Discount Card and Transitional Assistance Program on the date the individual's claim for the covered discount card drug is adjudicated.

(e) *Coinsurance.* If sufficient transitional assistance funds are available, transitional assistance funds must be expended in accordance with the following:

(1) For beneficiaries with incomes at or below 100 percent of the poverty line, 95 percent of the price of a covered discount card drug must be paid from the available transitional assistance funds.

(2) For beneficiaries with incomes greater than 100 percent but at or below 135 percent of the poverty line, 90 percent of the price of a covered discount card drug must be paid from the available transitional assistance funds.

(f) *Rollover.* An individual with transitional assistance retains access to any balance of transitional assistance not expended in a calendar year during the next calendar year, up to and including the transition period, if the individual—

(1) Remains in his or her current endorsed discount card program;

(2) Elects a new endorsed program in an Annual Coordinated Election Period; or

(3) Is eligible for a Special Election Period under § 403.811(b)(2) and elects a new endorsed discount card program during such Special Election Period.

§ 403.810 Eligibility and reconsiderations.

(a) *Eligibility for an endorsed discount card program.* An individual is eligible to enroll in an endorsed discount card program only if such individual meets the following conditions:

(1) The individual is entitled to benefits, or enrolled, under Medicare Part A or enrolled under Medicare Part B; and

(2) The individual, at the time of applying to enroll in an endorsed discount card program, is not enrolled in a State medical assistance program under Title XIX of the Act or under a waiver pursuant to section 1115 of the Act, under which the individual is entitled to any medical assistance for outpatient prescribed drugs as described in section 1905(a)(12) of the Act, except as allowed in § 403.817(d).

(b) *Eligibility for transitional assistance.* An individual is eligible to receive transitional assistance if, at the time of applying for transitional assistance, the individual meets the following conditions:

(1) The individual meets the conditions in paragraph (a) of this section;

(2) The individual resides in one of the 50 States or the District of Columbia;

(3) The individual's income is not more than 135 percent of the poverty line applicable to the individual's family size;

(4) The individual does not have coverage for covered discount card drugs under one or more of the following sources:

(i) A group health plan or health insurance coverage, as these terms are defined under section 2791 of the Public Health Service Act, other than a Part C plan or a group health plan consisting solely of excepted benefits (such as a Medigap plan) as the term is defined under section 2791 of the Public Health Service Act;

(ii) Coverage provided under Chapter 55 of Title 10, United States Code, including TRICARE; or

(iii) A Federal Employee's Health Benefits Program plan; and

(5) The individual (or the individual's authorized representative) completes a standard enrollment form and signs and dates the form in accordance with §403.811(a)(4). By signing the form, the individual (or the individual's authorized representative) certifies, under penalty of perjury, that, to the best of the individual's knowledge, the information he or she provides on the form is accurate.

(c) *Special rule for QMBs, SLMBs and QIs.* An individual is deemed to meet the income requirements in paragraph (b)(3) of this section if the individual is enrolled under Title XIX of the Act as a—

(1) Qualified Medicare Beneficiary (QMB);

(2) Specified Low-Income Medicare Beneficiary (SLMB); or

(3) Qualified Individual (QI).

(d) *Duration of eligibility determinations.* An individual determined eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, in the case of transitional assistance enrollees, for transitional assistance, shall remain eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, in the case of transitional assistance enrollees, for transitional assistance for the duration of the individual's enrollment in the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

(e) *Drug card and transitional assistance benefits not treated as benefits under other Federal programs.* Any benefits received under the Medicare Prescription Drug Discount Card and Transitional Assistance Program must not be taken into account in determining an individual's eligibility for, or the amount of benefits under, any other Federal program.

(f) *Verification of eligibility.* (1) CMS will verify eligibility to enroll in an endorsed discount card program or to receive transitional assistance.

(2) If CMS is unable to verify an individual's eligibility or ineligibility for transitional assistance, CMS can require the individual to provide additional income information in a form and manner specified by CMS as one condition of eligibility for transitional assistance.

(g) *Reconsideration.* (1) If an individual is determined ineligible to enroll in an endorsed discount card program under paragraph (a) of this section or determined ineligible to receive transitional assistance under paragraph (b) of this section, the individual (or the individual's authorized representative) has a right to request that an independent review entity under contract with CMS reconsider the determination.

(2) Reconsideration requests must be filed within 60 days from date of notice of an ineligibility determination, unless the individual (or the individual's authorized representative) can demonstrate good cause for why the 60-day time frame should be extended.

(3) An individual (or the individual's authorized representative) may submit additional documentary evidence or an explanation about his or her eligibility in writing to the independent review entity, as part of the reconsideration process.

(4) Reconsideration decisions shall be issued by the independent review entity in writing and contain an explanation of the reasoning of the decision.

§ 403.811 Enrollment and disenrollment and associated endorsed sponsor requirements.

(a) *Enrollment process.* (1) An individual (or an individual's authorized representative) applying to enroll in an endorsed discount card program must complete a standard enrollment form or other method allowed by CMS and provide such information to the endorsed discount card program in which the individual wishes to enroll.

(2) An individual electing to join an endorsed discount card program that charges an annual enrollment fee, and who is not applying for transitional assistance, must agree to pay the annual enrollment fee, if any, in a form and manner determined by the endorsed card sponsor.

(3) An individual applying for transitional assistance at the time that they apply for enrollment in an endorsed discount card program may only enroll in the endorsed discount card program at that time if CMS determines that the individual is eligible for transitional assistance. Individuals not found eligible for transitional assistance may enroll in an endorsed discount card program without applying for transitional assistance after being notified of their ineligibility for transitional assistance.

(4) An individual applying for transitional assistance must complete a standard enrollment form and sign and date the form, certifying, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the standard enrollment form.

(5) Except as provided in § 403.811(b)(4), an individual who is not currently enrolled in an endorsed card program seeking to enroll in the Medicare Prescription Drug Discount Card and Transitional Assistance Program may do so at any time during the enrollment period.

(6) An individual may not be enrolled in more than one endorsed discount card program at a time.

(7) An individual may enroll in only one endorsed discount card program per year during the enrollment period. An individual enrolling during the initial enrollment year, with the exception of the circumstances under paragraph (b)(2) of this section, may change election for the second enrollment year during the annual coordinated election period. During the second enrollment year, an individual may enroll in only one endorsed discount card program, unless the individual meets the circumstances described in paragraph (b)(2) of this section.

(8) An individual remains enrolled in an endorsed discount card program elected unless—

(i) The individual is disenrolled under paragraph (b) of this section;

(ii) The individual elects a new program during the Annual Coordinated Election Period; or

(iii) The endorsed sponsor terminates its endorsed discount card program, or is terminated.

(9) No new enrollment in an endorsed discount card program or changing election of an endorsed discount card program is allowed during the transition period.

(10) Except as specified in § 403.814(b)(6)(i), an individual may enroll in any endorsed discount card program, and only those endorsed discount card programs, offered in the individual's State of residence.

(11) In order to access negotiated prices or transitional assistance, if applicable, an individual must be enrolled in an endorsed discount card program. Access to negotiated prices begins with the effective date of enrollment and ends with disenrollment. Access to transitional assistance begins with the transitional assistance effective date and ends for claims finalized on the date of disenrollment.

(12) Except as provided in paragraph (b)(5) of this section, an individual may apply for transitional assistance at any time during the enrollment period.

(b) *Disenrollment process.* (1) An enrollee may voluntarily disenroll at any time by notifying (or by having his authorized representative notify) the endorsed sponsor.

(2) An enrolled individual who disenrolls during the enrollment period under the following circumstances is granted a Special Election Period in which the individual may enroll in another endorsed discount card program during the enrollment period:

(i) A move of residence outside the service area of the current program;

(ii) A change in residence to or from a long-term care facility;

(iii) Enrollment in or disenrollment from a Part C plan or Medicare cost plan;

(iv) An individual's current endorsed discount card program is terminated or terminates; or

(v) Other exceptional circumstances, as defined by the Secretary.

(3) Notification in order to effect a disenrollment is not required for an individual disenrolling from a terminating endorsed discount card program or enrolling in or disenrolling from a Medicare managed care plan offering an exclusive card program, or for individuals changing endorsed discount card programs during the Annual Coordinated Election Period.

(4) A drug discount card enrollee who disenrolls from an endorsed discount card program other than for one of the reasons listed in paragraph (b)(2) of this section will no longer be determined eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, if he or she disenrolls in 2004, must reapply for the Medicare Prescription Drug Discount Card and Transitional Assistance Program should he or she wish to enroll in another endorsed discount card program for the second enrollment year.

(5) An individual receiving transitional assistance who voluntarily disenrolls from an endorsed discount card program other than for one of the reasons listed in paragraph (b)(2) of this section will forfeit any transitional assistance remaining available to the individual on the date of disenrollment, and, if he or she disenrolls in 2004, must re-apply for transitional assistance for 2005 in order to receive transitional assistance in 2005.

(6) A discount card enrollee other than a transitional assistance enrollee may be involuntarily disenrolled from his or her endorsed discount card program for failure to pay the annual enrollment fee on a timely basis.

(7) A discount drug card enrollee other than a transitional assistance enrollee may be charged another annual enrollment fee each time the individual disenrolls from one endorsed discount card program and enrolls in another endorsed discount card program during the calendar year.

(c) *Enrollment fees.* (1) An endorsed sponsor may charge an annual enrollment fee of no more than $30 to each individual enrolled in its endorsed discount card program.

(2) An endorsed sponsor may not collect an enrollment fee from any individual applying for or receiving transitional assistance.

(3) The annual enrollment fee must not be prorated for portions of the year.

(4) An endorsed sponsor must charge a uniform enrollment fee to every discount card eligible individual, or to the Secretary in the case of individuals receiving transitional assistance, residing in a State.

(5) An endorsed sponsor must refund any enrollment fee collected from a discount card enrollee, or any State that has paid the enrollment fee on behalf of the discount card enrollee, during the calendar year during which the individual is determined eligible to receive transitional assistance.

(6) An endorsed sponsor may not charge an annual enrollment fee during the transition period.

§ 403.812 HIPAA privacy, security, administrative data standards, and national identifiers.

(a) *HIPAA covered entities.* An endorsed sponsor is a HIPAA covered entity and must comply with the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164 as set forth in this section. Those functions of a endorsed sponsor the performance of which are necessary or directly related to the operations of the endorsed discount card program are covered functions for purposes of applying to endorsed sponsors the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164.

(b) *HIPAA privacy requirements.* An endorsed sponsor must comply with the standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information, 45 CFR

parts 160 and 164, subparts A and E, in the same manner as a health plan, except to the extent such requirements are temporarily waived by the Secretary.

(c) *Security requirements.* (1) *Standard.* An endorsed sponsor must comply with the applicable standards, implementation specifications, and requirements in the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C, in the same manner as other covered entities as of the compliance date of such Rule.

(2) *Attestation.* An applicant in its application shall—

(i) Attest that, as of the initial enrollment date, it will have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information in accordance with 45 CFR 164.530(c); and

(ii) Attest that its information security measures will meet the standards, implementation specifications, and requirements of 45 CFR part 164 subparts A and C as of the initial enrollment date, or, if unable to make this attestation, provide a plan for coming into compliance with these requirements by the compliance date of the Security Rule set forth in 45 CFR part 164, subpart C.

(d) *Administrative data standards.* An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR parts 160 and 162 subparts I through R.

(e) *Unique identifiers.* An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements regarding standard unique identifiers under 45 CFR parts 160 and 162 as of the compliance date of any final rule for standard unique identifiers.

(f) *Applicability of other regulations.* Nothing in this paragraph or in § 403.813 shall be deemed a modification of parts 160, 162 and 164 of title 45, Code of Federal Regulations or otherwise modify the applicability of such regulations to other organizations or covered entities independently subject to the mandates of HIPAA. If an endorsed sponsor is also a health plan, health care provider, or health care clearinghouse, nothing is this paragraph shall impair or otherwise affect the application of HIPAA or parts 160, 162 and 164 of title 45, Code of Federal Regulations to such entity and its performance of those functions which make such entity a health plan, health care provider, or health care clearinghouse.

§ 403.813 Marketing limitations and record retention requirements.

(a) *Marketing limitations.* (1) An endorsed sponsor may only market the following:

(i) Those products and services offered under the endorsed program that are inside the scope of endorsement defined in § 403.806(h) and permitted under § 403.812(b).

(ii) A Part D plan offered by the endorsed sponsor or an affiliated organization of the endorsed sponsor.

(2) An endorsed sponsor may not request that a drug card enrollee or an individual seeking to enroll in its endorsed discount card program authorize the endorsed sponsor to use or disclose individually identifiable health information for purposes of marketing any product or service not allowed under paragraph (a)(1) of this section.

(3) An endorsed sponsor may not comingle any materials related to the marketing of products and services allowed under paragraph (a)(1) of this section with other marketing materials.

(4) Following termination of an endorsed sponsor's endorsement under §§ 403.820(c), (d) or (e) or termination of the Medicare Drug Discount Card and Transitional Assistance Program, a drug card enrollee's individually identifiable health information collected or maintained by an endorsed sponsor may not be used or disclosed for purposes of marketing any product or service.

(b) *Record retention standard.* (1) An endorsed sponsor must retain records that it creates, collects, or maintains while participating in the Medicare Drug Discount Card and Transitional Assistance Program as part of its operations of an endorsed program for at least 6 years following termination of

such program, or, in the event the endorsed sponsor's endorsement is terminated under § 420.820(c), (d), or (e) of this chapter at least 6 years following termination of such endorsement. The Secretary may extend the six-year retention period if an endorsed sponsor's records relate to an ongoing investigation, litigation, or negotiation by the Secretary, the Department of Health and Human Services Office of Inspector General, the Department of Justice, or a State, or such documents otherwise relate to suspicions of fraud and abuse or violations of Federal or State law.

(2) For the period during which an endorsed sponsor retains records as specified in paragraph (b)(1) of this section, an endorsed sponsor must continue to apply security and privacy protections to such records and the information contained therein to the same extent endorsed sponsors are required to do so under § 403.812(b) and § 403.812(c)(1) prior to termination.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52023, Sept. 1, 2005]

§ 403.814 Special rules concerning Part C organizations and Medicare cost plans and their enrollees.

(a) *General requirements.* (1) A Part C organization and Medicare cost plan may not require enrollment in an endorsed discount card program as a condition for enrollment in its Part C plan or Medicare cost plan.

(2) A Part C organization may subsidize the enrollment fee for an endorsed discount card program, whether operated by the Part C organization or another endorsed sponsor, for individuals described in § 403.810(a), provided that any such benefit is reflected in the Part C organization's Adjusted Community Rate filing.

(b) *Exclusive card sponsors.* (1) A Medicare managed care organization may elect to become an exclusive card sponsor by limiting enrollment in its endorsed discount card program to individuals described in § 403.810(a) who are enrolled in any of its Medicare managed care plans. The Medicare managed care organization must be the applicant for endorsement in order to offer an exclusive card program. Such an election must be made at the time of application for endorsement.

(2) Except as noted in paragraphs (b)(3) and (b)(4) of this section, an exclusive card sponsor must comply with all requirements for endorsed sponsors noted in § 403.804 and § 403.806.

(3) An exclusive card sponsor is deemed to meet or is exempt from certain specific requirements listed in § 403.806 as follows:

(i) An exclusive card sponsor is deemed to meet the pharmacy network requirement in § 403.806(f)(3) if its pharmacy network is not limited to mail-order pharmacies and is equivalent to the pharmacy network used in its Medicare managed care plan and such pharmacy network has been approved by the Secretary, or, if its Medicare managed care plan does not use a pharmacy network, the Secretary determines that the pharmacy network provides sufficient access to covered discount card drugs at negotiated prices for discount card enrollees under the standard set forth under 42 CFR 422.112 for a Part C organization described in section 1851(a)(2)(A) of the Act, or under 42 CFR 417.416(e) for a Medicare cost plan.

(ii) An exclusive card sponsor is deemed to meet the service area requirements in § 403.806(f)(1) and (f)(2) if it operates in a service area equivalent to its Medicare managed care plan's service area.

(iii) An exclusive card sponsor is deemed to meet the requirement for financial stability and business integrity in § 403.806(b) through compliance with § 422.400 of this chapter (if a Part C organization described in section 1851(a)(2)(A) of the Act) or compliance with § 417.120 and § 417.122 of this chapter (if a Medicare cost plan).

(iv) An exclusive card sponsor is deemed to meet the covered lives requirement in § 403.806(a)(3).

(v) An exclusive card sponsor is deemed to meet the requirements of § 403.806(e)(2) if it ensures that transitional assistance funds are applied to, and only to, the cost to transitional assistance enrollees of any covered discount card drugs obtained from a network or mail order pharmacy included in the exclusive card sponsor's pharmacy network, and at the option of the exclusive card sponsor, any covered discount card drug obtained under an

outpatient prescription drug benefit offered under the affiliated Medicare managed care plan, including any deductibles, co-payments, coinsurance, and other cost-sharing amounts for which transitional assistance enrollees are responsible under the Medicare managed care plan's outpatient prescription drug benefit.

(4) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in § 403.804 and § 403.806, except for the requirements in § 403.812 and § 403.813, may be waived or modified on behalf of an exclusive card sponsor if:

(i) The requirements are duplicative of or conflict with the requirements that a Medicare managed care organization must meet either under Part C or under section 1876 of Title XVIII of the Act; or

(ii) The waiver or modification is necessary to improve coordination between benefits under the Medicare Prescription Drug Discount Card and Transitional Assistance Program and the benefits either under Part C or under section 1876 of Title XVIII of the Act.

(iii) The applicant seeking to become an exclusive card sponsor requests such waivers or modifications in writing in a manner required by the Secretary.

(5) An exclusive card sponsor may conduct group enrollment according to the following rules:

(i) The exclusive card sponsor must seek CMS verification that its Medicare managed care members are individuals described in § 403.810(a) and enroll such individuals as a group into its exclusive card program.

(ii) The exclusive card sponsor must give all individuals it is enrolling as a group the opportunity to decline enrollment, and the opportunity to apply for transitional assistance.

(iii) The exclusive card sponsor may use a modified version of the standard enrollment form described in § 403.806(g)(3) or other CMS-approved process for group enrollment in its endorsed discount card program.

(6) An individual enrolled in a Medicare managed care plan offered by a Medicare managed care organization offering an exclusive card program to individuals enrolled in such Medicare managed care plan is subject to the following requirements:

(i) The individual may enroll only in the endorsed discount card program offered by his or her Medicare managed care organization.

(ii) If the exclusive card sponsor group elects to group enroll into an exclusive card program members of the Medicare managed plan, the individual must actively decline enrollment to avoid enrollment in the exclusive card program.

(c) *Non-uniformity of Benefits.* Implementation of the Medicare Prescription Drug Discount Card and Transitional Assistance Program, including the provision of transitional assistance and the payment or waiver of any enrollment fee by a Part C organization, will not be taken into account in applying the uniform premium and uniform benefits requirement in sections 1854(c) and 1854(f)(1)(D) of the Act and 42 CFR 422.100(d)(2) and 42 CFR 422.312(b)(2).

§ 403.815 Special rules concerning States.

(a) *Optional State payment of enrollment fee.* (1) A State may enter into payment arrangements with endorsed sponsors to provide payment of some or all of endorsed discount card programs' enrollment fees for some or all of the State's individuals described in § 403.810(a) who are not transitional assistance enrollees, provided the enrollment fees are paid directly by the State to the endorsed sponsor.

(2) Expenditures made by a State for enrollment fees described in paragraph (a)(1) of this section must not be treated as State expenditures for which Federal matching payments are available under titles XIX or XXI of the Act.

(b) *Optional State payment of coinsurance.* (1) A State may enter into payment arrangements with pharmacies to provide payment of some or all of coinsurance amounts described in § 403.808(e) for some or all of the State's transitional assistance enrollees, provided the coinsurance amounts are paid directly by the State to the pharmacy.

(2) Expenditures made by a State for coinsurance described in paragraph

(b)(1) of this section must not be treated as State expenditures for which Federal matching payments are available under titles XIX or XXI of the Act.

(c) *Coinsurance for Qualified Medicare Beneficiaries.* For transitional assistance enrollees who are qualified Medicare beneficiaries, any coinsurance liability under § 403.808(e) must not be treated as Medicare cost-sharing coinsurance, under section 1905(p)(3)(B) of the Act, for which a State would otherwise be required to pay.

(d) *State data.* (1) A State must provide data on a monthly basis in an electronic format as determined necessary by the Secretary to effectuate the verification of beneficiary eligibility for the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

(2) Expenditures made by a State in complying with the requirements of paragraph (d)(1) of this section will be treated as State expenditures for which Federal matching payments are available under section 1903(a)(7) of the Act.

§ 403.816 Special rules concerning long-term care and I/T/U pharmacies.

(a) *In general.* (1) An applicant for endorsement may submit an application to become a special endorsed sponsor for long-term care and/or for I/T/U pharmacies.

(2) Of qualified applicants, the Secretary will select at least two of the best-qualified applicants for special endorsement for long-term care and at least two of the best-qualified applicants for special endorsement for I/T/U pharmacies.

(3) Applicants for special endorsement for long-term care must demonstrate in their applications that they meet the requirements in paragraph (b) of this section.

(4) Applicants for special endorsement for I/T/U pharmacies must demonstrate in their applications that they meet the requirements in paragraph (d) of this section.

(b) *Long-term care.* A special endorsed sponsor for long-term care must—

(1) Apply transitional assistance toward the cost of covered discount card drugs obtained by transitional assistance enrollees who reside in long-term care facilities and who receive such prescription drugs through long-term care pharmacies;

(2) Offer contractual arrangements to any long-term care pharmacy seeking reimbursement from transitional assistance for covered discount card drugs provided by such pharmacy to transitional assistance enrollees who reside in long-term care facilities;

(3) Process any submitted claims from network pharmacies and out-of-network long-term care pharmacies that supply covered discount card drugs to transitional assistance enrollees who reside in long-term care facilities, when such enrollees have unspent transitional assistance remaining;

(4) Include special terms and conditions in its contracts with network pharmacies that are long-term care pharmacies to facilitate access to and the administration of transitional assistance to transitional assistance enrollees residing in long-term care facilities, including, but not limited to the following—

(i) Waiving penalties against long-term care pharmacies for submitting late claims to the special endorsed sponsor due to the pharmacy's coordination of benefits activities; and

(ii) Permitting a long-term care pharmacy to limit its services to only transitional assistance enrollees who reside in a long-term care facility served by the long-term care pharmacy.

(5) Except as noted in paragraph (c) of this section, comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(c) *Waiver of requirements.* (1) The following requirements will not apply to or will be waived for special endorsed sponsors providing transitional assistance to long-term care residents:

(i) Section 403.806(d) (relating to the prescription drug offering) shall not apply to long-term care pharmacies in the special endorsed sponsor's network; and

(ii) Section 403.806(e)(4) (requiring information about the amount of transitional assistance remaining) shall not apply to long-term care pharmacies in the special endorsed sponsor's network.

(2)(i) As the Secretary determines appropriate on a case-by-case basis, any

additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for long-term care if the waiver or modification is—

(A) Necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D–31 of the Act, or accommodate the unique needs of long-term care pharmacies; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for long-term care must request such waivers or modifications in writing in a manner required by the Secretary.

(d) *I/T/U pharmacies.* A special endorsed sponsor for I/T/U pharmacies must—

(1) Apply transitional assistance toward the cost of covered discount card drugs obtained by transitional assistance enrollees who are American Indians and Alaska Natives and who receive prescription drugs through I/T/U pharmacies as allowed under paragraph (d)(2) of this section;

(2) Offer contractual arrangements to any I/T/U pharmacy that is in the special endorsed sponsor's service area and seeking reimbursement from transitional assistance for covered discount card drugs provided by such pharmacy to transitional assistance enrollees who are also American Indians/Alaska Natives;

(3) Include special terms and conditions in its contracts with network I/T/U pharmacies to facilitate access to and the administration of transitional assistance for transitional assistance enrollees who are American Indians/Alaska Natives, including, but not limited to the following:

(i) Permitting an I/T/U pharmacy to limit its services to only those transitional assistance enrollees who are American Indians/Alaska Natives, and

(ii) Allowing an I/T/U pharmacy to select which drugs to stock, which may be a more limited set than other retail pharmacies.

(4) Except as noted in paragraph (e) of this section, comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(e) *Waiver of requirements.* (1) The following requirements will not apply to or will be waived for special endorsed sponsors providing transitional assistance through I/T/U pharmacies:

(i) Section 403.806(d) (relating to the prescription drug offering) shall not apply to I/T/U pharmacies in the special endorsed sponsor's network; and

(ii) Section 403.806(e)(4) (requiring information about the amount of transitional assistance remaining) shall not apply to I/T/U pharmacies in the special endorsed sponsor's network.

(2)(i) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for I/T/U pharmacies if the waiver or modification is—

(A) Necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D–31 of the Act, or accommodate the unique needs of I/T/U pharmacies; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for I/T/U pharmacies must request such waivers or modifications in writing in a manner required by the Secretary.

§ 403.817 Special rules concerning the territories.

(a) *In general.* (1) An applicant for endorsement may submit an application to become a special endorsed sponsor for all of the territories.

(2) Of qualified applicants, the Secretary will select at least one of the best-qualified applicants to receive a special endorsement for the territories.

(3) Applicants for special endorsement for the territories must demonstrate in their applications that they meet the requirements in paragraph (b) of this section.

(b) *Requirements.* (1) *Negotiated prices.* A special endorsed sponsor for residents of the territories must provide

access to negotiated prices in the territories.

(2) *Transitional assistance.* Any transitional assistance in the territories must be in accordance with paragraph (e) of this section.

(3) *Requirements, exception.* Except as specified in paragraph (c) of this section, a special endorsed sponsor for the territories must meet the requirements of §§ 403.804 and 403.806.

(c) *Waiver of requirements and alternative requirements.* (1) Section 403.806(d)(8) (requiring information about price differentials) shall not apply to pharmacies located in the territories and which are in the special endorsed sponsor's pharmacy network.

(2) Sections 403.806(f)(2) and (f)(3) will be deemed met if the special endorsed sponsor makes a good faith effort to secure the participation of retail and mail order pharmacies throughout a territory.

(3)(i) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for the territories if—

(A) Such waiver is necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D–31 of the Act, or accommodate the unique needs of pharmacies in the territories; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for the territories must request such waivers or modifications in writing in a manner required by the Secretary.

(d) *Other exceptions.* A special endorsed sponsor for the territories may enroll in its endorsed discount card program Medicaid enrollees with coverage for outpatient prescription drugs, as described in § 403.810(a)(2).

(e) *Transitional assistance provided by Territories.* (1) Transitional assistance in the territories may be administered only according to a plan submitted by a territory and approved by CMS.

(2) Territories choosing to provide transitional assistance must submit a plan to CMS within 90 days of the publication of this regulation. The plan must—

(i) Describe how funds allocated to the territory are to be used to cover the cost of covered discount card drugs obtained by individuals who reside in the territory, who are entitled to benefits under Medicare Part A or enrolled under Medicare Part B, and who have income at or below 135 percent of the poverty line for the contiguous United States; and

(ii) Describe how the territory will ensure that amounts received under the allotment are to be used only to provide covered discount card drugs to those individuals determined eligible for transitional assistance, as described in paragraph (e)(2)(i) of this section, and

(iii) Provide such written assurance for the requirements in paragraph (e)(2)(ii) of this section.

(3) CMS will review and approve plans submitted and make allotments to territories with approved plans.

(4) CMS may request reports or information to substantiate that the territories have administered the program consistent with the territory's approved transitional assistance plan.

§ 403.820 Sanctions, penalties, and termination.

(a) *Intermediate sanctions.* (1) For the violations listed in paragraph (a)(3) of this section, the following intermediate sanctions may be imposed on any endorsed sponsor:

(i) Suspension of enrollment of Medicare beneficiaries.

(ii) Suspension of information and outreach activities to Medicare beneficiaries.

(2) *Duration of sanctions.* The intermediate sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to recur.

(3) *Sanctionable violations.* The violations for which intermediate sanctions may be imposed are as follows:

(i) Substantial failure to maintain a contracted retail pharmacy network meeting the requirements of § 403.806(f);

(ii) Substantial failure to comply with CMS Information and Outreach Guidelines;

(iii) Substantial failure to provide discount card enrollees with negotiated prices consistent with information reported to CMS for the price comparison Web site and/or reported by the endorsed sponsor;

(iv) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), substantial failure to ensure that the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to changes in the card sponsor's cost structure (including material changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy);

(v) Charging drug card enrollees additional fees beyond a $30 enrollment fee;

(vi) Charging transitional assistance enrollees any enrollment fee;

(vii) Charging a coinsurance more than 5 percent for those at or below 100 percent of the poverty line, or 10 percent for those above 100 percent but at or below 135 percent of the poverty line;

(viii) Substantial failure to administer properly the transitional assistance funding for transitional assistance enrollees;

(ix) Substantial failure to provide CMS or its designees with requested information related to the endorsed sponsor's endorsed discount card operations; or

(x) Failure to otherwise substantially comply with the requirements of this subpart, including failing to perform the operational requirements of this program or the failure to submit an acceptable plan of correction within the timeframe specified by CMS.

(4) *Written notice of proposed sanctions.*

(i) Prior to imposing sanctions, CMS will send a written notice to the endorsed sponsor stating the nature and basis of the proposed sanction.

(ii) CMS will send a copy of the notice in paragraph (a)(4)(i) of this section to the Office of the Inspector General.

(iii) CMS will allow the endorsed sponsor 15 days from the receipt of notice to provide evidence that it has not committed an act or omission that may fairly be characterized as a basis for sanction.

(iv) Should an endorsed sponsor present evidence described in paragraph (a)(4)(iii) of this section and by the time limit described in that paragraph, a CMS official not involved in the original sanction determination shall review the evidence and provide the endorsed sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(5) *Effective date of sanction.*

(i) A sanction is effective 15 days after the date that the endorsed sponsor is notified of the sanction or, if the endorsed sponsor timely seeks reconsideration of that sanction decision, on the date specified in the notice of CMS's reconsideration determination.

(ii) The sanction remains in effect until CMS notifies the endorsed sponsor that CMS is satisfied that the basis for imposing the sanction has been corrected and is not likely to recur.

(b) *Civil monetary penalties.* (1) *OIG penalties.* The Office of the Inspector General (OIG) may impose civil monetary penalties in accordance with 42 CFR parts 1003 and 1005 in addition to, or in place of, sanctions that CMS may impose, as described in paragraph (a) of this section, against an endorsed sponsor whom it determines has knowingly—

(i) Misrepresented or falsified information in information and outreach or comparable material provided to program enrollee or other persons;

(ii) Charged a program enrollee in violation of the terms of the endorsement contract; or

(iii) Used transitional assistance funds in any manner that is inconsistent with the purpose of the transitional assistance program.

(2) *CMS penalties.* If CMS determines that an endorsed sponsor has engaged in conduct that it knows or should know constitutes a violation as described in paragraph (a)(3) of this section, where the failure to perform involves the operational requirements of the program, CMS may impose civil

monetary penalties in accordance with 42 CFR parts 1003 and 1005 in addition to, or in place of, the sanctions that CMS may impose, as described in paragraph (a) of this section.

(3) CMS or the OIG may impose civil monetary penalties of no more than $10,000 for each violation.

(c) *Termination of endorsement by CMS.* (1) CMS may terminate the endorsement contract at any time with notice on the following bases:

(i) Any of the bases for the imposition of intermediate sanctions as stated in paragraph (a)(3) of this section; or

(ii) The endorsed sponsor engaged in false or misleading information and outreach practices; or

(iii) The endorsed sponsor fails to comply with the requirement of § 403.804(e).

(2) CMS shall provide the endorsed sponsor written notice of termination 30 days prior to the CMS-determined effective date of the termination at which time the endorsed sponsor must do the following:

(i) Provide its discount card enrollees notice of the termination within 10 days of receiving notice from CMS;

(ii) Continue to provide services to its discount card enrollees for 90 days after the discount card enrollees were sent the notice of termination from the endorsed sponsor; and

(iii) Suspend all information and outreach and enrollment activities once enrollees have received the notice of termination.

(3) *Corrective action plan.* Before terminating a contract, CMS shall provide the endorsed sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(d) *Termination by endorsed sponsor*—(1) *Cause for termination.* The endorsed sponsor may terminate its endorsement contract if CMS fails substantially to carry out the terms of the contract.

(2) *Card sponsor notice.* The endorsed sponsor must give advance notice as follows:

(i) To CMS, at least 90 days prior to the intended date of termination. This notice must specify the reasons why the endorsed sponsor is requesting contract termination; and

(ii) To its discount card enrollees, by mail, at least 60 days prior to the termination effective date. This notice must include a written description of alternative endorsed discount card programs that serve the discount card enrollee's address.

(3) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the endorsed sponsor's notice of intent to terminate.

(e) *Termination by mutual consent.* (1) A contract may be modified or terminated at any time by written mutual consent.

(2) If the contract is terminated by mutual consent, the endorsed sponsor must provide notice to its discount card enrollees as provided in paragraph (d)(2) of this section.

(3) If the contract is modified by mutual consent, the endorsed sponsor must provide notice to its discount card enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(f) *Appeal of contract determinations.* (1) *Scope.* This section establishes the procedures for reviewing the following contract determinations:

(i) A determination that an applicant is not qualified to enter into a contract with CMS under section 1860D–31 of the Act; and

(i) A determination to terminate a contract with an endorsed sponsor in accordance with paragraph (c) of this section.

(2) *Notice of determination.* When CMS makes an initial contract determination, it gives the endorsed sponsor or applicant written notice specifying—

(i) The reasons for the determination; and

(ii) The endorsed sponsor's or applicant's right to request reconsideration.

(3) *Effect of contract determination.* The contract determination is final and binding unless a timely request for a reconsideration hearing is filed under this section.

(4) *Right to reconsideration.* An endorsed sponsor whose contract is terminated or an applicant denied endorsement may request a hearing for reconsideration of the CMS contract determination.

(5) *Method and place for filing a request.* A request for a reconsideration hearing must be made in writing and filed with the CMS Central Office.

(6) *Time for filing a request.* The request for a reconsideration hearing must be filed within 15 days from the date of the notice of the initial determination.

(7) *Appointment of hearing officer.* CMS shall appoint a hearing officer to conduct the reconsideration. The hearing officer shall be a representative of the Administrator and not otherwise a party to the contract determination.

(8) *Conduct of hearing.* The endorsed sponsor or applicant may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings will be made and transcribed.

(9) *Reconsideration determination.* A reconsideration determination is a new determination that—

(i) Is based on a review of the contract determination, the evidence and findings upon which it was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the endorsed sponsor subsequent to the contract determination; and

(ii) Affirms, reverses, or modifies the initial contract determination.

(10) *Notice of reconsidered determination.* As soon as practicable after the close of the hearing, the hearing officer issues a written reconsideration determination that contains the following:

(i) Findings with respect to the applicant's qualifications to enter into or an endorsed sponsor's qualifications to remain under a contract with CMS under section 1860D–31 of the Act;

(ii) A statement of the specific reasons for the reconsidered determination.

(11) *Effect of reconsidered determination.* A reconsidered determination is final and binding on the parties and is not subject to judicial review.

(g) *Compliance with HIPAA.* Failure of an endorsed sponsor to comply with HIPAA and/or the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164, as established in § 403.812, shall be a violation of HIPAA and may be enforced under sections 1176 and 1177 of the Act.

§ 403.822 Reimbursement of transitional assistance and associated sponsor requirements.

(a) A Transitional Assistance Account is created within the Federal Supplementary Medical Insurance Trust Fund and kept separate from all other funds within that fund.

(b) The Managing Trustee of the Transitional Assistance Account shall pay on a monthly basis from the Account the amounts certified by CMS as necessary to make payments for transitional assistance as allowed in § 403.808.

(c) Endorsed sponsors must routinely account to CMS for the transitional assistance provided to the transitional assistance enrollees for finalized (not pending, or denied) claims up to the allowed balance provided by CMS to the sponsor.

(d) Payment transactions will be audited by the Secretary or his agent.

(e) Federal funding in excess of the amount of the balance included in CMS's system is not permitted.

SUBCHAPTER B—MEDICARE PROGRAM

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AUTHORITY: Secs. 1102, 1861, 1862(a), 1871, 1874, 1881, and 1886(k) of the Social Security

Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart A [Reserved]

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

AUTHORITY: Secs. 1102, 1862 and 1871 of the Social Security Act as amended (42 U.S.C.1302, 1395y, and 1395hh).

SOURCE: 60 FR 48423, Sept. 19, 1995, unless otherwise noted.

§ 405.201 Scope of subpart and definitions.

(a) *Scope*. This subpart establishes that—

(1) CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as non-experimental/investigational (Category B).

(b) *Definitions*. As used in this subpart—

Class I refers to devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

Class II refers to devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

Class III refers to devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Contractors refers to carriers, fiscal intermediaries, and other entities that contract with CMS to review and adjudicate claims for Medicare services.

Experimental/investigational (Category A) device refers to an innovative device believed to be in Class III for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective).

IDE stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

Non-experimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

PMA stands for ''premarket approval'' and refers to a marketing application for a Class III device, which includes all information submitted with or incorporated by reference in the application in accordance with 21 U.S.C. 360e and 360j and 21 CFR 814.3(e).

Sponsor refers to a person or entity that initiates, but does not conduct, an investigation under an IDE.

§ 405.203 FDA categorization of investigational devices.

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Experimental/Investigational (Category A) Devices.

(2) Non-Experimental/Investigational (Category B) Devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).

(c) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

§ 405.205 Coverage of a non-experimental/investigational (Category B) device.

(a) For any device that meets the requirements of the exception at § 411.15(o) of this chapter, the following procedures apply:

(1) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).

(2) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at § 411.15(o) of this chapter, the FDA notifies the sponsor and CMS and the procedures described in paragraph (a)(2) of this section apply.

§ 405.207 Services related to a noncovered device.

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not ''reasonable'' and ''necessary'' under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for—

(1) Covered services to treat a condition or complication that arises due to the use of a noncovered device or a noncovered device-related service; or

(2) Routine care services related to experimental/investigational (Category A) devices as defined in § 405.201(b); and furnished in conjunction with an FDA-approved clinical trial. The trial must meet criteria established through the national coverage determination process; and if the trial is initiated before January 1, 2010, the device must be determined as intended for use in the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition.

(3) Routine care services related to a non-experimental/investigational (Category B) device defined in § 405.201(b) that is furnished in conjunction with an FDA-approved clinical trial.

[60 FR 48423, Sept. 19, 1995, as amended at 69 FR 66420, Nov. 15, 2004]

§ 405.209 Payment for a non-experimental/investigational (Category B) device.

Payment under Medicare for a non-experimental/investigational (Category B) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

§ 405.211 Procedures for Medicare contractors in making coverage decisions for a non-experimental/investigational (Category B) device.

(a) *General rule.* In their review of claims for payment, Medicare contractors are bound by the statute, regulations, and all CMS administrative issuances, including all national coverage decisions.

(b) *Potentially covered non-experimental/investigational (Category B) devices.* Medicare contractors may approve coverage for any device with an FDA-approved IDE categorized as a non-experimental/investigational (Category B) device if all other coverage requirements are met.

(c) *Other considerations.* Medicare contractors must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions for coverage have been placed on the device's use.

§ 405.213 Re-evaluation of a device categorization.

(a) *General rules.* (1) Any sponsor that does not agree with an FDA decision that categorizes its device as experimental/investigational (Category A) may request re-evaluation of the categorization decision.

(2) A sponsor may request review by CMS only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described in paragraph (b) of this section) nor CMS's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both CMS and the sponsor of its decision.

(c) *Request to CMS.* If the FDA does not agree to recategorize the device, the sponsor may seek review from CMS. A device sponsor must submit its request in writing to CMS. CMS obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. CMS reviews all material submitted by the sponsor and the FDA's recommendation. CMS reviews only information in the FDA record to determine whether to change the categorization of the device. CMS issues a written decision and notifies the sponsor of the IDE and the FDA.

§ 405.215 Confidential commercial and trade secret information.

To the extent that CMS relies on confidential commercial or trade secret information in any judicial proceeding, CMS will maintain confidentiality of the information in accordance with Federal law.

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

AUTHORITY: Secs. 1102, 1815, 1833, 1842, 1866, 1870, 1871, 1879, and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395cc, 1395gg, 1395hh, 1395pp, and 1395ccc) and 31 U.S.C. 3711.

SOURCE: 31 FR 13534, Oct. 20, 1966, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

GENERAL PROVISIONS

§ 405.301 Scope of subpart.

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

[54 FR 41733, Oct. 11, 1989]

LIABILITY FOR PAYMENTS TO PROVIDERS OR SUPPLIERS AND HANDLING OF INCORRECT PAYMENTS

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

Any payment made under title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.358 where:

(a) More than the correct amount is paid to a provider of services or other person and the Secretary determines that:

(1) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider of services or other person, or

(2) The provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(b) A payment has been made under the provisions described in section 1814(e) of the Act, to a provider of services for items and services furnished the individual.

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the third year following the year in

which notice was sent to such individual that such amount had been paid.

[41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 49271, Sept. 19, 1996]

§ 405.351 Incorrect payments for which the individual is not liable.

Where an incorrect payment has been made to a provider of services or other person, the individual is liable only to the extent that he has benefited from such payment.

§ 405.352 Adjustment of title XVIII incorrect payments.

Where an individual is liable for an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) adjustment is made (to the extent of such liability) by:

(a) Decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937, to which the individual is entitled; or

(b) In the event of the individual's death before adjustment is completed, by decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937 payable to the estate of the individual or to any other person, that are based on the individual's earnings record (or compensation).

[31 FR 13534, Oct. 20, 1966, as amended by 41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.353 Certification of amount that will be adjusted against individual title II or railroad retirement benefits.

As soon as practicable after any adjustment is determined to be necessary, the Secretary, for purposes of this subpart, shall certify the amount of the overpayment or payment (see § 405.350) with respect to which the adjustment is to be made. If the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1937, such certification shall be made to the Railroad Retirement Board.

§ 405.354 Procedures for adjustment or recovery—title II beneficiary.

The procedures applied in making an adjustment or recovery in the case of a title II beneficiary are the applicable procedures of 20 CFR 404.502.

[31 FR 13534, Oct. 20, 1966, as amended at 32 FR 18027, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.355 Waiver of adjustment or recovery.

(a) The provisions of § 405.352 may not be applied and there may be no adjustment or recovery of an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) in any case where such incorrect payment has been made with respect to an individual who is without fault, or where such adjustment or recovery would be made by decreasing payments to which another person who is without fault is entitled as provided in section 1870(b) of the Act where such adjustment or recovery would defeat the purpose of title II or title XVIII of the Act or would be against equity and good conscience. (See 20 CFR 404.509 and 404.512.)

(b) Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault shall be deemed to be against equity and good conscience if the determination that such payment was incorrect was made subsequent to the third year following the year in which notice of such payment was sent to such individual. (See §§ 405.330–405.332 for conditions under which payment may be made for items or services furnished after October 30, 1972 which are noncovered by reasons of § 405.310 (g) and (k).)

[41 FR 1493, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.356 Principles applied in waiver of adjustment or recovery.

The principles applied in determining waiver of adjustment or recovery (§ 405.355) are the applicable principles of § 405.358 and 20 CFR 404.507–404.509, 404.510a, and 404.512.

[61 FR 49271, Sept. 19, 1996]

§ 405.357 Notice of right to waiver consideration.

Whenever an initial determination is made that more than the correct

amount of payment has been made, notice of the provisions of section 1870(c) of the Act regarding waiver of adjustment or recovery shall be sent to the overpaid individual and to any other individual against whom adjustment or recovery of the overpayment is to be effected (see § 405.358).

[61 FR 49271, Sept. 19, 1996]

§ 405.358 When waiver of adjustment or recovery may be applied.

Section 1870(c) of the Act provides that there shall be no adjustment or recovery in any case where an incorrect payment under title XVIII (hospital and supplementary medical insurance benefits) has been made (including a payment under section 1814(e) of the Act with respect to an individual:

(a) Who is without fault, and

(b) Adjustment or recovery would either:

(1) Defeat the purposes of title II or title XVIII of the Act, or

(2) Be against equity and good conscience.

[61 FR 49271, Sept. 19, 1996]

§ 405.359 Liability of certifying or disbursing officer.

No certifying or disbursing officer shall be held liable for any amount certified or paid by him to any provider of services or other person:

(a) Where the adjustment or recovery of such amount is waived (see § 405.355), or

(b) Where adjustment (see § 405.352) or recovery is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

SUSPENSION AND RECOUPMENT OF PAYMENT TO PROVIDERS AND SUPPLIERS AND COLLECTION AND COMPROMISE OF OVERPAYMENTS

§ 405.370 Definitions.

For purposes of this subpart, the following definitions apply:

Offset. The recovery by Medicare of a non-Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. (Examples are Public Health Service debts or Medicaid debts recovered by CMS).

Recoupment. The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Suspension of payment. The withholding of payment by an intermediary or carrier from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists.

[61 FR 63745, Dec. 2, 1996]

§ 405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.

(a) *General*. Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be—

(1) Suspended, in whole or in part, by CMS, an intermediary, or a carrier if CMS, the intermediary, or the carrier possesses reliable information that an overpayment or fraud or willful misrepresentation exists or that the payments to be made may not be correct, although additional evidence may be needed for a determination; or

(2) Offset or recouped, in whole or in part, by an intermediary or a carrier if the intermediary, carrier, or CMS has determined that the provider or supplier to whom payments are to be made has been overpaid.

(b) *Steps necessary for suspension of payment, offset, and recoupment*. Except as provided in paragraph (c) of this section, CMS, the intermediary, or carrier suspends payments only after it has complied with the procedural requirements set forth at § 405.372. The intermediary or carrier offsets or recoups payments only after it has complied with the procedural requirements set forth at § 405.373.

(c) *Suspension of payment in the case of unfiled cost reports*. If a provider has failed to timely file an acceptable cost report, payment to the provider is immediately suspended in whole or in part until a cost report is filed and determined by the intermediary to be acceptable. In the case of an unfiled cost report, the provisions of § 405.372 do not

apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

[61 FR 63746, Dec. 2, 1996, as amended at 67 FR 66813, Nov. 1, 2002]

§ 405.372 Proceeding for suspension of payment.

(a) *Notice of intention to suspend*—(1) *General rule.* Except as provided in paragraphs (a)(2) through (a)(4) of this section, if the intermediary, carrier, or CMS has determined that a suspension of payments under § 405.371(a)(1) should be put into effect, the intermediary or carrier must notify the provider or supplier of the intention to suspend payments, in whole or in part, and the reasons for making the suspension.

(2) *Failure to furnish information.* The notice requirement of paragraph (a)(1) of this section does not apply if the intermediary or carrier suspends payments to a provider or supplier in accordance with section 1815(a) or section 1833(e) of the Act, respectively, because the provider or supplier has failed to submit information requested by the intermediary or carrier that is needed to determine the amounts due the provider or supplier. (See § 405.371(c) concerning failure to file timely acceptable cost reports.)

(3) *Harm to Trust Funds.* A suspension of payment may be imposed without prior notice if CMS, the intermediary, or carrier determines that the Medicare Trust Funds would be harmed by giving prior notice. CMS may base its determination on an intermediary's or carrier's belief that giving prior notice would hinder the possibility of recovering the money.

(4) *Fraud or misrepresentation.* If the intended suspension of payment involves suspected fraud or misrepresentation, CMS determines whether to impose the suspension and if prior notice is appropriate. CMS directs the intermediary or carrier as to the timing and content of the notification to the provider or supplier. CMS is the real party in interest and is responsible for the decision. CMS may base its decision on information from the intermediary, carrier, law enforcement agencies, or other sources. CMS determines whether the information is reliable.

(b) *Rebuttal*—(1) *If prior notice is required.* If prior notice is required under paragraph (a) of this section, the intermediary or carrier must give the provider or supplier an opportunity for rebuttal in accordance with § 405.374. If a rebuttal statement is received within the specified time period, the suspension of payment goes into effect on the date stated in the notice, and the procedures and provisions set forth in § 405.375 apply. If by the end of the period specified in the notice no statement has been received, the suspension goes into effect automatically, and the procedures set forth in paragraph (c) of this section are followed.

(2) *If prior notice is not required.* If, under the provisions of paragraphs (a)(2) through (a)(4) of this section, a suspension of payment is put into effect without prior notice to the provider or supplier, the intermediary or carrier must, once the suspension is in effect, give the provider or supplier an opportunity to submit a rebuttal statement as to why the suspension should be removed.

(c) *Subsequent action.* If a suspension of payment is put into effect, the intermediary, carrier, or CMS takes timely action after the suspension to obtain the additional evidence it may need to make a determination as to whether an overpayment exists or the payments may be made. The intermediary, carrier, or CMS makes all reasonable efforts to expedite the determination. As soon as the determination is made, the intermediary or carrier informs the provider or supplier and, if appropriate, the suspension is rescinded or any existing recoupment or offset is adjusted to take into account the determination.

(d) *Duration of suspension of payment*—(1) *General rule.* Except as provided in paragraphs (d)(2) and (d)(3) of this section, a suspension of payment is limited to 180 days, starting with the date the suspension begins.

(2) *180-day extension.* (i) An intermediary, a carrier, or, in cases of fraud and misrepresentation, OIG or a law enforcement agency, may request a one-time only extension of the suspension period for up to 180 additional days if it is unable to complete its examination of the information or investigation, as appropriate, within the 180-

day time limit. The request must be submitted in writing to CMS.

(ii) Upon receipt of a request for an extension, CMS notifies the provider or supplier of the requested extension. CMS then either extends the suspension of payment for up to an additional 180 days or determines that the suspended payments are to be released to the provider or supplier.

(3) *Exceptions to the time limits.* (i) The time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply if the case has been referred to, and is being considered by, the OIG for administrative action (for example, civil money penalties).

(ii) CMS may grant an extension in addition to the extension provided under paragraph (d)(2) of this section if the Department of Justice submits a written request to CMS that the suspension of payment be continued based on the ongoing investigation and anticipated filing of criminal and/or civil actions. At a minimum, the request must include the following:

(A) Identification of the entity under suspension.

(B) The amount of time needed for continued suspension in order to implement the criminal and/or civil proceedings.

(C) A statement of why and/or how criminal and/or civil actions may be affected if the requested extension is not granted.

(e) *Disposition of suspended payments.* Payments suspended under the authority of § 405.371(b) are first applied to reduce or eliminate any overpayments determined by the intermediary, carrier, or CMS, including any interest assessed under the provisions of § 405.378, and then applied to reduce any other obligation to CMS or to HHS. In the absence of a legal requirement that the excess be paid to another entity, the excess is released to the provider or supplier.

[61 FR 63746, Dec. 2, 1996]

§ 405.373 Proceeding for offset or recoupment.

(a) *General rule.* Except as specified in paragraph (b) of this section, if the intermediary, carrier, or CMS has determined that an offset or recoupment of payments under § 405.371(a)(2) should be put into effect, the intermediary or carrier must—

(1) Notify the provider or supplier of its intention to offset or recoup payment, in whole or in part, and the reasons for making the offset or recoupment; and

(2) Give the provider or supplier an opportunity for rebuttal in accordance with § 405.374.

(b) Paragraph (a) of this section does not apply if the intermediary, after furnishing a provider a written notice of the amount of program reimbursement in accordance with § 405.1803, recoups payment under paragraph (c) of § 405.1803. (For provider rights in this circumstance, see §§ 405.1809, 405.1811, 405.1815, 405.1835, and 405.1843.)

(c) *Actions following receipt of rebuttal statement.* If a provider or supplier submits, in accordance with § 405.374, a statement as to why an offset or recoupment should not be put into effect on the date specified in the notice, the intermediary or carrier must comply with the time limits and notification requirements of § 405.375.

(d) *No rebuttal statement received.* If, by the end of the time period specified in the notice, no statement has been received, the recoupment or offset goes into effect automatically.

(e) *Duration of recoupment or offset.* If a recoupment or offset is put into effect, it remains in effect until the earliest of the following:

(1) The overpayment and any assessed interest are liquidated.

(2) The intermediary or carrier obtains a satisfactory agreement from the provider or supplier for liquidation of the overpayment.

(3) The intermediary or carrier, on the basis of subsequently acquired evidence or otherwise, determines that there is no overpayment.

[61 FR 63747, Dec. 2, 1996]

§ 405.374 Opportunity for rebuttal.

(a) *General rule.* If prior notice of the suspension of payment, offset, or recoupment is given under § 405.372 or § 405.373, the intermediary or carrier must give the provider or supplier an opportunity, before the suspension, offset, or recoupment takes effect, to submit any statement (to include any pertinent information) as to why it should

not be put into effect on the date specified in the notice. Except as provided in paragraph (b) of this section, the provider or supplier has at least 15 days following the date of notification to submit the statement.

(b) *Exception*. The intermediary or carrier may for cause—

(1) Impose a shorter period for rebuttal; or

(2) Extend the time within which the statement must be submitted.

[61 FR 63747, Dec. 2, 1996]

§ 405.375 Time limits for, and notification of, administrative determination after receipt of rebuttal statement.

(a) *Submission and disposition of evidence*. If the provider or supplier submits a statement, under § 405.374, as to why a suspension of payment, offset, or recoupment should not be put into effect, or, under § 405.372(b)(2), why a suspension should be terminated, CMS, the intermediary, or carrier must within 15 days, from the date the statement is received, consider the statement (including any pertinent evidence submitted), together with any other material bearing upon the case, and determine whether the facts justify the suspension, offset, or recoupment or, if already initiated, justify the termination of the suspension, offset, or recoupment. Suspension, offset, or recoupment is not delayed beyond the date stated in the notice in order to review the statement.

(b) *Notification of determination*. The intermediary or carrier must send written notice of the determination made under paragraph (a) of this section to the provider or supplier. The notice must—

(1) In the case of offset or recoupment, contain rationale for the determination; and

(2) In the case of suspension of payment, contain specific findings on the conditions upon which the suspension is initiated, continued, or removed and an explanatory statement of the determination.

(c) *Determination is not appealable*. A determination made under paragraph (a) of this section is not an initial determination and is not appealable.

[61 FR 63747, Dec. 2, 1996]

§ 405.376 Suspension and termination of collection action and compromise of claims for overpayment.

(a) *Basis and purpose*. This section contains requirements and procedures for the compromise of, or suspension or termination of collection action on, claims for overpayments against a provider or a supplier under the Medicare program. It is adopted under the authority of the Federal Claims Collection Act (31 U.S.C. 3711). Collection and compromise of claims against Medicare beneficiaries are explained at 20 CFR 404.515.

(b) *Definitions*. As used in this section, *debtor* means a provider of services or a physician or other supplier of services that has been overpaid under title XVIII of the Social Security Act. It includes an individual, partnership, corporation, estate, trust, or other legal entity.

(c) *Basic conditions*. A claim for recovery of Medicare overpayments against a debtor may be compromised, or collection action on it may be suspended or terminated, by the Centers for Medicare & Medicaid Services (CMS) if;

(1) The claim does not exceed $100,000, or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest; and

(2) There is no indication of fraud, the filing of a false claim, or misrepresentation on the part of the debtor or any director, partner, manager, or other party having an interest in the claim.

(d) *Basis for compromise*. A claim may be compromised for one or more of the following reasons:

(1) The debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount within a reasonable time;

(2) The debtor refuses to pay the claim in full and the United States is unable to collect the full amount within a reasonable time by legal proceedings;

(3) There is real doubt the United States can prove its case in court; or

(4) The cost of collecting the claim does not justify enforced collection of the full amount.

(e) *Basis for termination of collection action.* Collection action may be terminated for one or more of the following reasons:

(1) The United States cannot enforce collection of any significant sum;

(2) The debtor cannot be located, there is no security to be liquidated, the statute of limitations has run, and the prospects of collecting by offset are too remote to justify retention of the claim;

(3) The cost of further collection action is likely to exceed any recovery;

(4) It is determined the claim is without merit; or

(5) Evidence to substantiate the claim is no longer available.

(f) *Basis for suspension of collection action.* Collection action may be suspended for either of the following reasons if future collection action is justified based on potential productivity, including foreseeable ability to pay, and size of claim:

(1) The debtor cannot be located; or

(2) The debtor is unable to make payments on the claim or to fulfill an acceptable compromise.

(g) *Factors considered.* In determining whether a claim will be compromised, or collection action terminated or suspended, CMS will consider the following factors:

(1) Age and health of the debtor, present and potential income, inheritance prospects, possible concealment or fraudulent transfer of assets, and the availability of assets which may be reached by enforced collection proceedings, for compromise under paragraph (d)(1) of this section, termination under paragraph (e)(1) of this section, and suspension under paragraph (f)(2) of this section;

(2) Applicable exemptions available to a debtor and uncertainty concerning the price of the property in a forced sale, for compromise under paragraph (d)(2) of this section and termination under paragraph (e)(1) of this section; and

(3) The probability of proving the claim in court, the probability of full or partial recovery, the availability of necessary evidence, and related pragmatic considerations, for compromise under paragraph (d)(3) of this section.

(h) *Amount of compromise.* The amount accepted in compromise will be reasonable in relation to the amount that can be recovered by enforced collection proceedings.

Consideration shall be given to the following:

(1) The exemptions available to the debtor under State or Federal law;

(2) The time necessary to collect the overpayment;

(3) The litigative probabilities involved; and

(4) The administrative and litigative costs of collection where the cost of collecting the claim is a basis for compromise.

(i) *Payment of compromise*—(1) *Time and manner.* Payment of the amount that CMS has agreed to accept as a compromise in full settlement of a Medicare overpayment claim must be made within the time and in the manner prescribed by CMS. An overpayment claim is not compromised or settled until the full payment of the compromised amount has been made within the time and in the manner prescribed by CMS.

(2) *Failure to pay compromised amount.* Failure of the debtor or the estate to make payment as provided by the comprise reinstates the full amount of the overpayment claim, less any amounts paid prior to the default.

(j) *Effect of compromise, or suspension, or termination of collection action.* Any action taken by CMS under this section regarding the compromise of an overpayment claim, or termination or suspension of collection action on an overpayment claim, is not an initial determination for purposes of the appeal procedures under subparts G, H, and R of this part.

[43 FR 59381, Dec. 20, 1978, as amended at 57 56998, Dec. 2, 1992. Redesignated and amended at 61 FR 63745, 63747, Dec. 2, 1996]

§ 405.377 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* This section implements section 1885 of the Act, which provides for withholding Medicare payments to certain Medicaid providers that have not arranged to repay Medicaid overpayments as determined by the Medicaid State agency or have

failed to provide information necessary to determine the amount (if any) of overpayments.

(b) *When withholding may be used.* CMS may withhold Medicare payment to offset Medicaid overpayments that a Medicaid agency has been unable to collect if—

(1) The Medicaid agency has followed the procedure specified in §447.31 of this chapter; and

(2) The institution or person is one described in paragraph (c) of this section and either—

(i) Has not made arrangements satisfactory to the Medicaid agency to repay the overpayment; or

(ii) Has not provided information to the Medicaid agency necessary to enable the agency to determine the existence or amount of Medicaid overpayment.

(c) *Institutions or persons affected.* Withholding under paragraph (b) of this section may be made with respect to any of the following entities that has or had in effect an agreement with a Medicaid agency to furnish services under an approved Medicaid State plan:

(1) An institutional provider that has in effect an agreement under section 1866 of the Act. (Part 489 (Provider and Supplier Agreements) implements section 1866 of the Act.)

(2) A physician or supplier that has accepted payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act. (Section 424.55 sets forth the conditions a supplier agrees to in accepting assignment.)

(d) *Amount to be withheld.* (1) CMS contacts the appropriate intermediary or carrier to determine the amount of Medicare payment to which the institution or person is entitled.

(2) CMS may require the intermediary or carrier to withhold Medicare payments to the institution or person by the lesser of the following amounts:

(i) The amount of the Medicare payments to which the institution or person would otherwise be entitled.

(ii) The total Medicaid overpayment to the institution or person.

(e) *Notice of withholding.* If CMS intends to withhold payments under this section, it notifies by certified mail, return receipt requested, the institution or person and the appropriate intermediary or carrier of the intention to withhold Medicare payments and follows the procedure in §405.374. The notice includes—

(1) Identification of the institution or person; and

(2) The amount of Medicaid overpayment to be withheld from payments to which the institution or person would otherwise be entitled under Medicare.

(f) *Termination of withholding.* CMS terminates the withholding if—

(1) The Medicaid overpayment is completely recovered;

(2) The institution or person enters into an agreement satisfactory to the Medicaid agency to repay the overpayment; or

(3) The Medicaid agency determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(g) *Disposition of funds withheld.* CMS releases amounts withheld under this section to the Medicaid agency to be applied against the Medicaid overpayment made by the State agency.

[61 FR 63747, Dec. 2, 1996]

§405.378 Interest charges on overpayment and underpayments to providers, suppliers, and other entities.

(a) *Basis and purpose.* This section, which implements sections 1815(d) and 1833(j) of the common law and Act, and authority granted under the Federal Claims Collection Act, provides for the charging and payment of interest on overpayments and underpayments to Medicare providers, suppliers, HMOs, competitive medical plans (CMPs), and health care prepayment plans (HCPPs).

(b) *Basic rules.* (1) CMS will charge interest on overpayments, and pay interest on underpayments, to providers and suppliers of services (including physicians and other practitioners), except as specified in paragraphs (f) and (h) of this section.

(2) Interest accrues from the date of the final determination as defined in paragraph (c) of this section, and either is charged on the overpayment balance or paid on the underpayment balance for each full 30-day period that payment is delayed.

(c) *Definition of final determination.* (1) For purposes of this section, any of the

following constitutes a final determination:

(i) A Notice of Amount of Program Reimbursement (NPR) is issued, as discussed in §§ 405.1803, 417.576, and 417.810, and either—

(A) A written demand for payment is made; or

(B) A written determination of an underpayment is made by the intermediary after a cost report is filed.

(ii) In cases in which an NPR is not used as a notice of determination (that is, primarily under part B), one of the following determinations is issued—

(A) A written determination that an overpayment exists and a written demand for payment;

(B) A written determination of an underpayment; or

(C) An Administrative Law Judge (ALJ) decision that reduces the amount of an overpayment below the amount that CMS has already collected.

(iii) Other examples of cases in which an NPR is not used are carrier reasonable charge determinations under subpart E of this part, interim cost settlements made for HMOs, CMPs, and HCPPs under §§ 417.574 and 417.810(e) of this chapter, and initial retroactive adjustment determinations under § 413.64(f)(2) of this chapter. In the case of interim cost settlements and initial retroactive adjustment determinations, if the debtor does not dispute the adjustment determination within the timeframe designated in the notice of the determination (generally at least 15 days), a final determination is deemed to have been made. If the provider or supplier does dispute portions of the determination, a final determination is deemed to have been made on those portions when the intermediary issues a new determination in response to the dispute.

(iv) The due date of a timely-filed cost report that indicates an amount is due CMS, and is not accompanied by payment in full. (If an additional overpayment or underpayment is determined by the carrier or intermediary, a final determination on the additional amount is made in accordance with paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii), of this section.)

(v) With respect to a cost report that is not filed on time, the day following the date the cost report was due (plus a single extension of time not to exceed 30 days if granted for good cause), until the time as a cost report is filed. (When the cost report is subsequently filed, there is an additional determination as specified in paragraphs (c)(1) (i), (ii), (iii), or (iv) of this section.)

(2) Except as required by any subsequent administrative or judicial reversal, interest accrues from the date of final determination as specified in this subsection.

(d) *Rate of interest.* (1) The interest rate on overpayments and underpayments is the higher of—

(i) The rate as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of final determination as defined in paragraph (c) of this section (this rate is published quarterly in the FEDERAL REGISTER by the Department under 45 CFR 30.13(a)); or

(ii) The current value of funds rate (this rate is published annually in the FEDERAL REGISTER by the Secretary of the Treasury, subject to quarterly revisions).

(2) [Reserved]

(e) *Accrual of interest.* (1) If a cost report is filed that does not indicate an amount is due CMS but the intermediary makes a final determination that an overpayment exists, or if a carrier makes a final determination that an overpayment to a physician or supplier exists, interest will accrue beginning with the date of such final determination. Interest will continue to accrue during periods of administrative and judicial appeal and until final disposition of the claim.

(2)(i) If a cost report is filed and indicates that an amount is due CMS, interest on the amount due will accrue from the due date of the cost report unless—

(A) Full payment on the amount due accompanies the cost report; or

(B) The provider and the intermediary agree in advance to liquidate the overpayment through a reduction in interim payments over the next 30-day period.

(ii) If the intermediary determines an additional overpayment during the cost settlement process, interest will accrue from the date of each determination.

(iii) The interest rate on each of the final determinations of an overpayment will be the rate of interest in effect on the date the determination is made.

(3) In the case of a cost report that is not filed on time, interest also will accrue on a determined overpayment from the day following the due date of the report (plus a single extension of time not to exceed 30 days if granted for good cause, as specified in § 413.24(f)) of this chapter, to the time the cost report is filed.

(4) If an intermediary or a carrier makes a final determination that an underpayment exists, interest to the provider or the supplier will accrue from the date of notification of the underpayment.

(f) *Waiver of interest charges.* (1) When an intermediary or a carrier makes a final determination that an overpayment or underpayment exists, as specified in paragraphs (e)(1), (e)(2)(ii), and (e)(4)—

(i) Interest charges will be waived if the overpayment or underpayment is completely liquidated within 30 days from the date of the final determination.

(ii) CMS may waive interest charges if it determines that the administrative cost of collecting them exceeds the interest charges.

(2) Interest will not be waived for that period of time during which the cost report was due but remained unfiled for more than 30 days, as specified in paragraph (e)(3) of this section.

(g) *Rules applicable to partial payments.* If an overpayment is repaid in installments or recouped by withholding from several payments due the provider or supplier of services—

(1) Each payment or recoupment will be applied first to accrued interest and then to the principal; and

(2) After each payment or recoupment, interest will accrue on the remaining unpaid balance.

(h) *Exceptions to applicability.* (1) The provisions of this section do not apply to the time period for which interest is payable under § 413.64(j) of this chapter because the provider seeks judicial review of a decision of the Provider Reimbursement Review Board, or a subsequent reversal, affirmance, or modification of that decision by the Administrator. Prior to that time, until the provider seeks judicial review, interest accrues at the rate specified in this section on outstanding unpaid balances resulting from final determinations as defined in paragraph (c) of this section.

(2) If an overpayment or an underpayment determination is reversed administratively or judicially, and the reversal is no longer subject to appeal, appropriate adjustments will be made with respect to the overpayment or underpayment and the amount of interest charged.

(i) *Nonallowable cost.* As specified in §§ 412.113 and 413.153 of this chapter, interest accrued on overpayments and interest on funds borrowed specifically to repay overpayments are not considered allowable costs, up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (for example, capital improvements).

(See § 413.153(a)(2) of this chapter for exceptions based on administrative or judicial reversal.)

[47 FR 54814, Dec. 6, 1982, as amended at 49 FR 36102, Sept. 14, 1984; 49 FR 44472, Nov. 7, 1984; 51 FR 34792, Sept. 30, 1986; 56 FR 31336, July 10, 1991. Redesignated at 61 FR 63745, Dec. 2, 1996; 69 FR 45607, July 30, 2004]

REPAYMENT OF SCHOLARSHIPS AND LOANS

§ 405.380 Collection of past-due amounts on scholarship and loan programs.

(a) *Basis and purpose.* This section implements section 1892 of the Act, which authorizes the Secretary to deduct from Medicare payments for services amounts considered as past-due obligations under the National Health Service Corps Scholarship program, the Physician Shortage Area Scholarship program, and the Health Education Assistance Loan program.

(b) *Offsetting against Medicare payment.* (1) Medicare carriers and intermediaries offset against Medicare payments in accordance with the signed

repayment agreement between the Public Health Service and individuals who have breached their scholarship or loan obligations and who—

(i) Accept Medicare assignment for services;

(ii) Are employed by or affiliated with a provider, HMO, or Competitive Medical Plan (CMP) that receives Medicare payment for services; or

(iii) Are members of a group practice that receives Medicare payment for services.

(2) For purposes of this section, ''provider'' includes all entities eligible to receive Medicare payment in accordance with an agreement under section 1866 of the Act.

(c) *Beginning of offset.* (1) The Medicare carrier offsets Medicare payments beginning six months after it notifies the individual or the group practice of the amount to be deducted and the particular individual to whom the deductions are attributable.

(2) The Medicare intermediary offsets payments beginning six months after it notifies the provider, HMO, CMP or group practice of the amount to be deducted and the particular individuals to whom the deductions are attributable. Offset of payments is made in accordance with the terms of the repayment agreement. If the individual ceases to be employed by the provider, HMO, or CMP, or leaves the group practice, no deduction is made.

(d) *Refusal to offset against Medicare payment.* If the individual refuses to enter into a repayment agreement, or breaches any provision of the agreement, or if Medicare payment is insufficient to maintain the offset collection according to the agreed upon formula, then—

(1) The Department, within 30 days if feasible, informs the Attorney General; and

(2) The Department excludes the individual from Medicare until the entire past due obligation has been repaid, unless the individual is a sole community practitioner or the sole source of essential specialized services in a community and the State requests that the individual not be excluded.

[57 FR 19092, May 4, 1992]

Subpart D—Private Contracts

AUTHORITY: Secs. 1102, 1802, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395a, and 1395hh).

SOURCE: 63 FR 58901, Nov. 2, 1998, unless otherwise noted.

§ 405.400 Definitions.

For purposes of this subpart, the following definitions apply:

Beneficiary means an individual who is enrolled in Part B of Medicare.

Emergency care services means services furnished to an individual for treatment of an ''emergency medical condition'' as that term is defined in § 422.2 of this chapter.

Legal representative means one or more individuals who, as determined by applicable State law, has the legal authority to enter into the contract with the physician or practitioner on behalf of the beneficiary.

Opt-out means the status of meeting the conditions specified in § 405.410.

Opt-out period means the 2-year period beginning on the effective date of the affidavit as specified by § 405.410(c)(1) or § 405.410(c)(2), as applicable.

Participating physician means a ''physician'' as defined in this section who has signed an agreement to participate in Part B of Medicare.

Physician means a doctor of medicine; doctor of osteopathy; doctor of dental surgery or of dental medicine; doctor of podiatric medicine; or doctor of optometry who is legally authorized to practice medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, or optometry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions.

Practitioner means a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, or clinical social worker, who is currently legally authorized to practice in that capacity by each State in which he or she furnishes services to patients or clients.

Private contract means a document that meets the criteria specified in § 405.415.

Properly opt-out means to complete, without defect, the requirements for opt-out as specified in § 405.410.

Properly terminate opt-out means to complete, without defect, the requirements for terminating opt-out as specified in § 405.445.

Urgent care services means services furnished to an individual who requires services to be furnished within 12 hours in order to avoid the likely onset of an emergency medical condition.

[63 FR 58901, Nov. 2, 1998, as amended at 69 FR 1116, Jan. 7, 2004]

§ 405.405 General rules.

(a) A physician or practitioner may enter into one or more private contracts with Medicare beneficiaries for the purpose of furnishing items or services that would otherwise be covered by Medicare, provided the conditions of this subpart are met.

(b) A physician or practitioner who enters into at least one private contract with a Medicare beneficiary under the conditions of this subpart, and who submits one or more affidavits in accordance with this subpart, opts-out of Medicare for a 2-year period unless the opt-out is terminated early according to § 405.445. The physician's or practitioner's opt-out may be renewed for subsequent 2-year periods.

(c) Both the private contracts described in paragraph (a) of this section and the physician's or practitioner's opt-out described in paragraph (b) of this section are null and void if the physician or practitioner fails to properly opt-out in accordance with the conditions of this subpart.

(d) Both the private contracts described in paragraph (a) of this section and the physician's or practitioner's opt-out described in paragraph (b) of this section are null and void for the remainder of the opt-out period if the physician or practitioner fails to remain in compliance with the conditions of this subpart during the opt-out period.

(e) Services furnished under private contracts meeting the requirements of this subpart are not covered services under Medicare, and no Medicare payment will be made for such services either directly or indirectly, except as permitted in accordance with § 405.435(c).

§ 405.410 Conditions for properly opting-out of Medicare.

The following conditions must be met for a physician or practitioner to properly opt-out of Medicare:

(a) Each private contract between a physician or a practitioner and a Medicare beneficiary that is entered into prior to the submission of the affidavit described in paragraph (b) of this section must meet the specifications of § 405.415.

(b) The physician or practitioner must submit an affidavit that meets the specifications of § 405.420 to each Medicare carrier with which he or she would file claims absent completion of opt-out.

(c) A nonparticipating physician or a practitioner may opt-out of Medicare at any time in accordance with the following:

(1) The 2-year opt-out period begins the date the affidavit meeting the requirements of § 405.420 is signed, provided the affidavit is filed within 10 days after he or she signs his or her first private contract with a Medicare beneficiary.

(2) If the physician or practitioner does not timely file any required affidavit, the 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

(d) A participating physician may properly opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in § 405.420 is submitted to the participating physician's Medicare carriers at least 30 days before the beginning of the selected calendar quarter. A private contract entered into before the beginning of the selected calendar quarter becomes effective at the beginning of the selected calendar quarter and the furnishing of any items or services to a Medicare beneficiary

under such contract before the beginning of the selected calendar quarter is subject to standard Medicare rules.

§ 405.415 Requirements of the private contract.

A private contract under this subpart must:

(a) Be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract.

(b) Clearly state whether the physician or practitioner is excluded from Medicare under sections 1128, 1156, or 1892 or any other section of the Social Security Act.

(c) State that the beneficiary or his or her legal representative accepts full responsibility for payment of the physician's or practitioner's charge for all services furnished by the physician or practitioner.

(d) State that the beneficiary or his or her legal representative understands that Medicare limits do not apply to what the physician or practitioner may charge for items or services furnished by the physician or practitioner.

(e) State that the beneficiary or his or her legal representative agrees not to submit a claim to Medicare or to ask the physician or practitioner to submit a claim to Medicare.

(f) State that the beneficiary or his or her legal representative understands that Medicare payment will not be made for any items or services furnished by the physician or practitioner that would have otherwise been covered by Medicare if there was no private contract and a proper Medicare claim had been submitted.

(g) State that the beneficiary or his or her legal representative enters into this contract with the knowledge that he or she has the right to obtain Medicare-covered items and services from physicians and practitioners who have not opted-out of Medicare, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted-out.

(h) State the expected or known effective date and expected or known expiration date of the opt-out period.

(i) State that the beneficiary or his or her legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare.

(j) Be signed by the beneficiary or his or her legal representative and by the physician or practitioner.

(k) Not be entered into by the beneficiary or by the beneficiary's legal representative during a time when the beneficiary requires emergency care services or urgent care services. (However, a physician or practitioner may furnish emergency or urgent care services to a Medicare beneficiary in accordance with § 405.440.)

(l) Be provided (a photocopy is permissible) to the beneficiary or to his or her legal representative before items or services are furnished to the beneficiary under the terms of the contract.

(m) Be retained (original signatures of both parties required) by the physician or practitioner for the duration of the opt-out period.

(n) Be made available to CMS upon request.

(o) Be entered into for each opt-out period.

§ 405.420 Requirements of the opt-out affidavit.

An affidavit under this subpart must:

(a) Be in writing and be signed by the physician or practitioner.

(b) Contain the physician's or practitioner's full name, address, telephone number, national provider identifier (NPI) or billing number, if one has been assigned, uniform provider identification number (UPIN) if one has been assigned, or, if neither an NPI nor a UPIN has been assigned, the physician's or practitioner's tax identification number (TIN).

(c) State that, except for emergency or urgent care services (as specified in § 405.440), during the opt-out period the physician or practitioner will provide services to Medicare beneficiaries only through private contracts that meet the criteria of paragraph § 405.415 for services that, but for their provision under a private contract, would have been Medicare-covered services.

(d) State that the physician or practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-

out period, nor will the physician or practitioner permit any entity acting on his or her behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in § 405.440.

(e) State that, during the opt-out period, the physician or practitioner understands that he or she may receive no direct or indirect Medicare payment for services that he or she furnishes to Medicare beneficiaries with whom he or she has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare+Choice plan.

(f) State that a physician or practitioner who opts-out of Medicare acknowledges that, during the opt-out period, his or her services are not covered under Medicare and that no Medicare payment may be made to any entity for his or her services, directly or on a capitated basis.

(g) State a promise by the physician or practitioner to the effect that, during the opt-out period, the physician or practitioner agrees to be bound by the terms of both the affidavit and the private contracts that he or she has entered into.

(h) Acknowledge that the physician or practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the physician or practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom he or she has not previously privately contracted) without regard to any payment arrangements the physician or practitioner may make.

(i) With respect to a physician who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit.

(j) Acknowledge that the physician or practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of § 405.440 apply if the physician furnishes such services.

§ 405.425 Effects of opting-out of Medicare.

If a physician or practitioner opts-out of Medicare in accordance with this subpart for the 2-year period for which the opt-out is effective, the following results obtain:

(a) Except as provided in § 405.440, no payment may be made directly by Medicare or by any Medicare+Choice plan to the physician or practitioner or to any entity to which the physician or practitioner reassigns his right to receive payment for services.

(b) The physician or practitioner may not furnish any item or service that would otherwise be covered by Medicare (except for emergency or urgent care services) to any Medicare beneficiary except through a private contract that meets the requirements of this subpart.

(c) The physician or practitioner is not subject to the requirement to submit a claim for items or services furnished to a Medicare beneficiary, as specified in § 424.5(a)(6) of this chapter, except as provided in § 405.440.

(d) The physician or practitioner is prohibited from submitting a claim to Medicare for items or services furnished to a Medicare beneficiary except as provided in § 405.440.

(e) In the case of a physician, he or she is not subject to the limiting charge provisions of § 414.48 of this chapter, except for services provided under § 405.440.

(f) The physician or practitioner is not subject to the prohibition-on-reassignment provisions of § 414.80 of this chapter, except for services provided under § 405.440.

(g) In the case of a practitioner, he or she is not prohibited from billing or collecting amounts from beneficiaries (as provided in 42 U.S.C. 1395u(b)(18)(B)).

(h) The death of a beneficiary who has entered into a private contract (or whose legal representative has done so) does not invoke § 424.62 or § 424.64 of this chapter with respect to the physician or practitioner with whom the

beneficiary (or legal representative) has privately contracted.

(i) The physician or practitioner who has not been excluded under sections 1128, 1156, or 1892 of the Social Security Act may order, certify the need for, or refer a beneficiary for Medicare-covered items and services, provided the physician or practitioner is not paid, directly or indirectly, for such services (except as provided in § 405.440).

(j) The physician or practitioner who is excluded under sections 1128, 1156, or 1892 of the Social Security Act may not order, prescribe, or certify the need for Medicare-covered items and services except as provided in § 1001.1901 of this title, and must otherwise comply with the terms of the exclusion in accordance with § 1001.1901 effective with the date of the exclusion.

§ 405.430 Failure to properly opt-out.

(a) A physician or practitioner fails to properly opt-out if—

(1) Any private contract between the physician or practitioner and a Medicare beneficiary, that was entered into before the affidavit described in § 405.420 was filed, does not meet the specifications of § 405.415; or

(2) He or she fails to submit the affidavit(s) in accordance with § 405.420.

(b) If a physician or practitioner fails to properly opt-out in accordance with paragraph (a) of this section, the following results obtain:

(1) The physician's or practitioner's attempt to opt-out of Medicare is nullified, and all of the private contracts between the physician or practitioner and Medicare beneficiaries for the two-year period covered by the attempted opt-out are deemed null and void.

(2) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries, including the items and services furnished under the nullified contracts. A nonparticipating physician is subject to the limiting charge provisions of § 414.48 of this chapter. A participating physician is subject to the limitations on charges of the participation agreement he or she signed.

(3) The practitioner may not reassign any claim except as provided in § 424.80 of this chapter.

(4) The practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts.

(5) The physician or practitioner may make another attempt to properly opt-out at any time.

§ 405.435 Failure to maintain opt-out.

(a) A physician or practitioner fails to maintain opt-out under this subpart if, during the opt-out period—

(1) He or she knowingly and willfully—

(i) Submits a claim for Medicare payment (except as provided in § 405.440); or

(ii) Receives Medicare payment directly or indirectly for Medicare-covered services furnished to a Medicare beneficiary (except as provided in § 405.440).

(2) He or she fails to enter into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare, or enters into contracts that fail to meet the specifications of § 405.415; or

(3) He or she fails to comply with the provisions of § 405.440 regarding billing for emergency care services or urgent care services; or

(4) He or she fails to retain a copy of each private contract that he or she has entered into for the duration of the opt-out period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

(b) If a physician or practitioner fails to maintain opt-out in accordance with paragraph (a) of this section, and fails to demonstrate, within 45 days of a notice from the carrier of a violation of paragraph (a) of this section, that he or she has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract), the following results obtain, effective 46 days after the date of the notice, but only for the remainder of the opt-out period:

(1) All of the private contracts between the physician or practitioner and Medicare beneficiaries are deemed null and void.

(2) The physician's or practitioner's opt-out of Medicare is nullified.

(3) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.

(4) The physician or practitioner or beneficiary will not receive Medicare payment on Medicare claims for the remainder of the opt-out period, except as provided in paragraph (c) of this section.

(5) The physician is subject to the limiting charge provisions of § 414.48 of this chapter.

(6) The practitioner may not reassign any claim except as provided in § 424.80 of this chapter.

(7) The practitioner may neither bill nor collect any amount from the beneficiary except for applicable deductible and coinsurance amounts.

(8) The physician or practitioner may not attempt to once more meet the criteria for properly opting-out until the 2-year opt-out period expires.

(c) Medicare payment may be made for the claims submitted by a beneficiary for the services of an opt-out physician or practitioner when the physician or practitioner did not privately contract with the beneficiary for services that were not emergency care services or urgent care services and that were furnished no later than 15 days after the date of a notice by the carrier that the physician or practitioner has opted-out of Medicare.

§ 405.440 Emergency and urgent care services.

(a) A physician or practitioner who has opted-out of Medicare under this subpart need not enter into a private contract to furnish emergency care services or urgent care services to a Medicare beneficiary. Accordingly, a physician or practitioner will not be determined to have failed to maintain opt-out if he or she furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, provided the physician or practitioner complies with the billing requirements specified in paragraph (b) of this section.

(b) When a physician or practitioner who has not been excluded under sections 1128, 1156, or 1892 of the Social Security Act furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, he or she:

(1) Must submit a claim to Medicare in accordance with both 42 CFR part 424 and Medicare instructions (including but not limited to complying with proper coding of emergency or urgent care services furnished by physicians and practitioners who have opted-out of Medicare).

(2) May collect no more than—

(i) The Medicare limiting charge, in the case of a physician; or

(ii) The deductible and coinsurance, in the case of a practitioner.

(c) Emergency care services or urgent care services furnished to a Medicare beneficiary with whom the physician or practitioner has previously entered into a private contract (that is, entered into before the onset of the emergency medical condition or urgent medical condition), are furnished under the terms of the private contract.

(d) Medicare may make payment for emergency care services or urgent care services furnished by a physician or practitioner who has properly opted-out when the services are furnished and the claim for services is made in accordance with this section. A physician or practitioner who has been excluded must comply with the regulations at § 1001.1901 (Scope and effect of exclusion) of this title when he or she furnishes emergency services to beneficiaries and may not bill and be paid for urgent care services.

§ 405.445 Renewal and early termination of opt-out.

(a) A physician or practitioner may renew opt-out by filing an affidavit with each carrier with which he or she would file claims absent completion of opt-out, provided the affidavits are filed within 30 days after the current opt-out period expires.

(b) To properly terminate opt-out a physician or practitioner must:

(1) Not have previously opted out of Medicare.

(2) Notify all Medicare carriers, with which he or she filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the opt-out period.

(3) Refund to each beneficiary with whom he or she has privately contracted all payment collected in excess of:

(i) The Medicare limiting charge (in the case of physicians); or

(ii) The deductible and coinsurance (in the case of practitioners).

(4) Notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's or practitioner's decision to terminate opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period.

(c) When the physician or practitioner properly terminates opt-out in accordance with paragraph (b), he or she will be reinstated in Medicare as if there had been no opt-out, and the provision of § 405.425 shall not apply unless the physician or practitioner subsequently properly opts out.

(d) A physician or practitioner who has completed opt-out on or before January 1, 1999 may terminate opt-out during the 90 days following January 1, 1999 if he or she notifies all carriers to whom he or she would otherwise submit claims of the intent to terminate opt-out and complies with paragraphs (b)(3) and (4) of this section. Paragraph (c) of this section applies in these cases.

§ 405.450 Appeals.

(a) A determination by CMS that a physician or practitioner has failed to properly opt-out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, or failed to properly terminate opt-out is an initial determination for purposes of § 405.803.

(b) A determination by CMS that no payment can be made to a beneficiary for the services of a physician who has opted-out is an initial determination for purposes of § 405.803.

§ 405.455 Application to Medicare+Choice contracts.

An organization that has a contract with CMS to provide one or more Medicare+Choice (M+C) plans to beneficiaries (part 422 of this chapter):

(a) Must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted-out of Medicare.

(b) Must make no payment directly or indirectly for Medicare covered services furnished to a Medicare beneficiary by a physician or practitioner who has opted-out of Medicare.

(c) May make payment to a physician or practitioner who furnishes emergency or urgent care services to a beneficiary who has not previously entered into a private contract with the physician or practitioner in accordance with § 405.440.

Subpart E—Criteria for Determining Reasonable Charges

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 32 FR 12599, Aug. 31, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.500 Basis.

Subpart E is based on the provisions of the following sections of the Act: Section 1814(b) provides for Part A payment on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1832 establishes the scope of benefits provided under the Part B supplementary medical insurance program. Section 1833(a) sets forth the amounts of payment for supplementary medical insurance services on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1834(a) specifies how payments are made for the purchase or rental of new and used durable medical equipment for Medicare beneficiaries. Section 1834(b) provides for payment for radiologist services on a fee schedule basis. Section 1834(c) provides for payments and standards for screening mammography. Section 1842(b) sets forth the provisions for a carrier to enter into a contract with the Secretary and to make determinations

with respect to Part B claims. Section 1842(h) sets forth the requirements for a physician or supplier to voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. Section 1842(i) sets forth the provisions for the payment of Part B claims. Section 1848 establishes a fee schedule for payment of physician services. Section 1861(b) sets forth the inpatient hospital services covered by the Medicare program. Section 1861(s) sets forth medical and other health services covered by the Medicare program. Section 1861(v) sets forth the general authority under which CMS may establish limits on provider costs recognized as reasonable in determining Medicare program payments. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program. Section 1861(jj) defines the term ''covered osteoporosis drug.'' Section 1862(a)(14) lists services that are excluded from coverage. Section 1866(a) specifies the terms for provider agreements. Section 1881 authorizes special rules for the coverage of and payment for services furnished to patients with end-stage renal disease. Section 1886 sets forth the requirements for payment to hospitals for inpatient hospital services. Section 1887 sets forth requirements for payment of provider-based physicians and payment under certain percentage arrangements. Section 1889 provides for Medicare and Medigap information by telephone.

[60 FR 63175, Dec. 8, 1995]

§ 405.501 Determination of reasonable charges.

(a) Except as specified in paragraphs (b), (c), and (d) of this section, Medicare pays no more for Part B medical and other health services than the ''reasonable charge'' for such service. The reasonable charge is determined by the carriers (subject to any deductible and coinsurance amounts as specified in §§ 410.152 and 410.160 of this chapter).

(b) Part B of Medicare pays on the basis of ''reasonable cost'' (see part 413 of this chapter) for certain institutional services, certain services furnished under arrangements with institutions, and services furnished by entities that elect to be paid on a cost basis (including health maintenance organizations, rural health clinics, Federally qualified health centers and end-stage renal disease facilities).

(c) Carriers will determine the reasonable charge on the basis of the criteria specified in § 405.502, and the customary and prevailing charge screens in effect when the service was furnished. (Also see §§ 415.55 through 415.70 and §§ 415.100 through 415.130 of this chapter, which pertain to the determination of reimbursement for services performed by hospital-based physicians.) However, when services are furnished more than 12 months before the beginning of the fee screen year (January 1 through December 30) in which a request for payment is made, payment is based on the customary and prevailing charge screens in effect for the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is made.

(d) Payment under Medicare Part B for durable medical equipment and prosthetic and orthotic devices is determined in accordance with the provisions of subpart D of part 414 of this chapter.

[47 FR 63274, Dec. 31, 1981, as amended at 51 FR 34978, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986; 54 FR 9003, Mar. 2, 1989; 57 FR 24975, June 12, 1992; 57 FR 33896, July 31, 1992; 57 FR 57688, Dec. 7, 1992; 60 FR 63176, Dec. 8, 1995]

§ 405.502 Criteria for determining reasonable charges.

(a) Criteria. The law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for. The criteria for determining what charges are reasonable include:

(1) The customary charges for similar services generally made by the physician or other person furnishing such services.

(2) The prevailing charges in the locality for similar services.

(3) In the case of physicians' services, the prevailing charges adjusted to reflect economic changes as provided under § 405.504 of this subpart.

(4) In the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services), the inflation-indexed charge as determined under § 405.509.

(5) [Reserved]

(6) In the case of medical services, supplies, and equipment (including equipment servicing) that the Secretary judges do not generally vary significantly in quality from one supplier to another, the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality.

(7) Other factors that may be found necessary and appropriate with respect to a category of service to use in judging whether the charge is inherently reasonable. This includes special reasonable charge limits (which may be either upper or lower limits) established by CMS or a carrier if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in the grossly deficient or excessive charges. The determination of these limits is described in paragraphs (g) and (h) of this section.

(8) In the case of laboratory services billed by a physician but performed by an outside laboratory, the payment levels established in accordance with the criteria stated in § 405.515.

(9) Except as provided in paragraph (a)(10) of this section, in the case of services of assistants-at-surgery as defined in § 405.580 in teaching and nonteaching settings, charges that are not more than 16 percent of the prevailing charge in the locality, adjusted by the economic index, for the surgical procedure performed by the primary surgeon. Payment is prohibited for the services of an assistant-at-surgery in surgical procedures for which CMS has determined that assistants-at-surgery on average are used in less than 5 percent of such procedures nationally.

(10) In the case of services of assistants at surgery that meet the exception under § 415.190(c)(2) or (c)(3) of this chapter because the physician is performing a unique, necessary, specialized medical service in the total care of a patient during surgery, reasonable charges consistent with prevailing practice in the carrier's service area rather than the special assistant at surgery rate.

(b) *Comparable services limitation*. The law also specifies that the reasonable charge cannot be higher than the charge applicable for a comparable service under comparable circumstances to the carriers' own policyholders and subscribers.

(c) *Application of criteria*. In applying these criteria, the carriers are to exercise judgment based on factual data on the charges made by physicians to patients generally and by other persons to the public in general and on special factors that may exist in individual cases so that determinations of reasonable charge are realistic and equitable.

(d) *Responsibility of Administration and carriers*. Determinations by carriers of reasonable charge are not reviewed on a case-by-case basis by the Centers for Medicare & Medicaid Services, although the general procedures and performance of functions by carriers are evaluated. In making determinations, carriers apply the provisions of the law under broad principles issued by the Centers for Medicare & Medicaid Services. These principles are intended to assure overall consistency among carriers in their determinations of reasonable charge. The principles in §§ 405.503 through 405.507 establish the criteria for making such determinations in accordance with the statutory provisions.

(e) *Determination of reasonable charges under the End-Stage Renal Disease (ESRD) Program*—(1) *General*. Reasonable charges for renal-related items and services (furnished in connection with transplantation or dialysis) must be related to costs and allowances that are reasonable when the treatments are furnished in an effective and economical manner.

(2) *Nonprovider (independent) dialysis facilities*. Reasonable charges for renal-related items and services furnished before August 1, 1983 must be determined related to costs and charges prior to July, 1973, in accordance with the regulations at § 405.541. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(3) *Provider services and (hospital-based) dialysis facilities.* Renal-related items and services furnished by providers, or by ESRD facilities based in hospitals, before August 1, 1983 are paid for under the provider reimbursement provisions found generally in part 413 of this chapter. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(4) *Physicians' services.* Reasonable charges for renal-related physicians' services must be determined considering charges made for other services involving comparable physicians' time and skill requirements, in accordance with regulations at §§ 405.542 and 405.543.

(5) *Health maintenance organizations (HMOs).* For special rules concerning the reimbursement of ESRD services furnished by risk-basis HMOs, or by facilities owned or operated by or related to such HMOs by common ownership or control, see §§ 405.2042(b)(14) and 405.2050(c).

(f) *Determining payments for certain physician services furnished in outpatient hospital settings*—(1) *General rule.* If physician services of the type routinely furnished in physicians' offices are furnished in outpatient hospital settings before January 1, 1992, carriers determine the reasonable charge for those services by applying the limits described in paragraph (f)(5) of this section.

(2) *Definition.* As used in this paragraph (f), *outpatient settings* means—

(i) Hospital outpatient departments, including clinics and emergency rooms; and

(ii) Comprehensive outpatient rehabilitation facilities.

(3) *Services covered by limits.* The carrier establishes a list of services routinely furnished in physicians' offices in the area. The carrier has the discretion to determine which professional services are routinely furnished in physicians' offices, based on current medical practice in the area. Listed below are some examples of routine services furnished by office-based physicians.

Examples

Review of recent history, determination of blood pressure, ausculation of heart and lungs, and adjustment of medication.

Brief history and examination, and initiation of diagnostic and treatment programs.

Treatment of an acute respiratory infection.

(4) *Services excluded from limits.* The limits established under this paragraph do not apply to the following:

(i) Rural health clinic services.

(ii) Surgical services included on the ambulatory surgical center list of procedures published under § 416.65(c) of this chapter.

(iii) Services furnished in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) Placing the patient's health in serious jeopardy;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(iv) Anesthesiology services and diagnostic and therapeutic radiology services.

(v) Federally qualified health center services paid under the rules in part 405 subpart X.

(5) *Methodology for developing limits*—(i) *Development of a charge base.* The carrier establishes a charge base for each service identified as a routine office-based physician service. The charge base consists of the prevailing charge in the locality for each such service adjusted by the economic index. The carrier uses the prevailing charges that apply to services by nonspecialists in office practices in the locality in which the outpatient setting is located.

(ii) *Calculation of the outpatient limits.* The carrier calculates the charge limit for each service by multiplying the charge base amount for each service by .60.

(6) *Application of limits.* The reasonable charge for physician services of the type described in paragraph (f)(3) of this section that are furnished in an outpatient setting is the lowest of the

actual charges, the customary charges in accordance with § 405.503, the prevailing charges applicable to these services in accordance with § 405.504, or the charge limits calculated in paragraph (f)(5)(ii) of this section.

(g) *Determination of payment amounts in special circumstances*—(1) *General.* (i) For purposes of this paragraph, a ''category of items or services'' may consist of a single item or service or any number of items or services.

(ii) CMS or a carrier may determine that the standard rules for calculating payment amounts set forth in this subpart for a category of items or services identified in section 1861(s) of the Act (other than physician services paid under section 1848 of the Act and those items and services for which payment is made under a prospective payment system, such as outpatient hospital or home health) will result in grossly deficient or excessive amounts. A payment amount will not be considered grossly excessive or deficient if it is determined that an overall payment adjustment of less than 15 percent is necessary to produce a realistic and equitable payment amount. For CMS initiated adjustments, CMS will publish in the FEDERAL REGISTER an analysis of payment adjustments that exceed $100 million per year in compliance with Executive Order 12866. If CMS makes adjustments that have a significant effect on a substantial number of small entities, it will publish an analysis in compliance with the Regulatory Flexibility Act.

(iii) If CMS or the carrier determines that the standard rules for calculating payment amounts for a category of items or services will result in grossly deficient or excessive amounts, CMS, or the carrier, may establish special payment limits that are realistic and equitable for a category of items or services. If CMS makes a determination, it is considered a national determination. A carrier determination is one made by a carrier/intermediary or groups of carriers/intermediaries even if the determination applies to all State fees.

(iv) The limit on the payment amount is either an upper limit to correct a grossly excessive payment amount or a lower limit to correct a grossly deficient payment amount.

(v) The limit is either a specific dollar amount or is based on a special method to be used in determining the payment amount.

(vi) Except as provided in paragraph (h) of this section, a payment limit for a given year may not vary by more than 15 percent from the payment amount established for the preceding year.

(vii) *Examples of excessive or deficient payment amounts.* Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to, the following:

(A) The marketplace is not competitive. This includes circumstances in which the marketplace for a category of items or services is not truly competitive because a limited number of suppliers furnish the item or service.

(B) Medicare and Medicaid are the sole or primary sources of payment for a category of items or services.

(C) The payment amounts for a category of items or services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.

(D) The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities for the category of items or services, taking into account the relative costs of furnishing the category of items or services in the different localities.

(E) Payment amounts for a category of items or services are grossly higher or lower than acquisition or production costs for the category of items or services.

(F) There have been increases in payment amounts for a category of items or services that cannot be explained by inflation or technology.

(G) The payment amounts for a category of items or services are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality.

(H) A new technology exists which is not reflected in the existing payment allowances.

(2) *Establishing a limit*. In establishing a payment limit for a category of items or services, CMS or a carrier considers the available information that is relevant to the category of items or services and establishes a payment amount that is realistic and equitable. The factors CMS or a carrier consider in establishing a specific dollar amount or special payment method for a category of items or services may include, but are not limited to, the following:

(i) *Price markup*. This is the relationship between the retail and wholesale prices or manufacturer's costs of a category of items or services. If information on a particular category of items or services is not available, CMS or a carrier may consider the markup on a similar category of items or services and information on general industry pricing trends.

(ii) *Differences in charges*. CMS or a carrier may consider the differences in charges for a category of items or services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii) *Costs*. CMS or a carrier may consider resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items or services.

(iv) *Use*. CMS or a carrier may impute a reasonable rate of use for a category of items or services and consider unit costs based on efficient use.

(v) *Payment amounts in other localities*. CMS or a carrier may consider payment amounts for a category of items or services furnished in another locality.

(3) *Notification of limits*—(i) *National limits*. CMS publishes in the FEDERAL REGISTER proposed and final notices announcing a special payment limit described in paragraph (g) of this section before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to a payment limit for a category of items or services.

(ii)(A) *Carrier-level limits*. A carrier proposing to establish a special payment limit for a category of items or services must inform the affected suppliers and Medicaid agencies of the proposed payment amounts, the factors it considered in proposing the particular limit, as described in paragraphs (g)(1) through (g)(4) of this section, and solicit comments. The notice must also consider the following:

(*1*) The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.

(*2*) What entities would be affected such as classes of providers or suppliers and beneficiaries.

(*3*) How significantly would these entities be affected.

(*4*) How would the adjustment affect beneficiary access to items or services.

(B) The carrier must evaluate the comments it receives. The carrier must notify CMS in writing of any final limits it plans to establish. CMS will acknowledge in writing to the carrier that it received the carrier's notification. After the carrier has received CMS's acknowledgement, the carrier must inform the affected suppliers and State Medicaid agencies of any final limits it establishes. The effective date for a final payment limit may apply to services furnished at least 60 days after the date that the carrier notifies affected suppliers and State Medicaid agencies of the final limit.

(4) *Use of valid and reliable data*. In determining whether a payment amount is excessive or deficient and in establishing an appropriate payment amount, valid and reliable data will be used. To ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i) Develop written guidelines for data collection and analysis;

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

(5) If CMS or a carrier makes a payment adjustment of more than 15 percent spread over multiple years, CMS or the carrier will review market prices in the years subsequent to the year that the initial reduction is effective in order to ensure that further reductions continue to be appropriate.

(h) *Special payment limit adjustments greater than 15 percent of the payment amount.* In addition to applying the general rules under paragraphs (g)(1) through (g)(4) of this section, CMS applies the following rules in establishing a payment adjustment greater than 15 percent of the payment amount for a category of items or services within a year:

(1) *Potential impact of special limit.* CMS considers the potential impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

(2) *Supplier consultation.* Before making a determination that a payment amount for a category of items or services is not inherently reasonable by reason of its grossly excessive or deficient amount, CMS consults with representatives of the supplier industry likely to be affected by the change in the payment amount.

(3) *Publication of national limits.* If CMS determines under paragraph (h) of this section to establish a special payment limit for a category of items or services, it publishes in the FEDERAL REGISTER the proposed and final notices of a special payment limit before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to the limit for the category of items or services.

(i) *Proposed notice.* The proposed notice—

(A) Explains the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B) Specifies the proposed payment amount or methodology to be established for a category of items or services;

(C) Explains the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D) Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E) Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments.

(i) *Paramedic intercept ambulance services.* (1) CMS establishes its payment allowance on a carrier-wide basis by using the median allowance from all localities within an individual carrier's jurisdiction.

(2) CMS's payment allowance is equal to the advanced life support rate minus 40 percent of the basic life support rate.

(3) CMS bases payment on the lower of the actual charge or the amount described in paragraph (i)(1) and (i)(2) of this section.

(Secs. 1102, 1814(b), 1833(a), 1842(b), and (h), and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, as amended, 79 Stat. 296, 302, 310, 331; 86 Stat. 1395, 1454; 42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1).

[32 FR 12599, Aug. 31, 1967]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 405.502, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and on GPO Access.

§ 405.503 Determining customary charges.

(a) *Customary charge defined.* The term ''customary charges'' will refer to the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service. In determining such uniform amount, token charges for charity patients and substandard charges for welfare and other low income patients are to be excluded. The reasonable charge cannot, except as provided in § 405.506, be higher than the individual physician's or other person's customary charge. The customary charge for different physicians or other persons may, of course, vary. Payment for covered services would be based on the actual charge for the service when, in a given instance, that charge is less than the amount which the carrier would otherwise have found to be within the limits of acceptable charges for the particular service. Moreover, the income of the individual beneficiary is not to be taken into account by the carrier in determining the amount which is considered to be a reasonable charge for a service rendered to him. There is no provision in the law for a carrier to evaluate the reasonableness of charges in light of an individual beneficiary's economic status.

(b) *Variation of charges.* If the individual physician or other person varies his charges for a specific medical procedure or service, so that no one amount is charged in the majority of cases, it will be necessary for the carrier to exercise judgment in the establishment of a ''customary charge'' for such physician or other person. In making this judgment, an important guide, to be utilized when a sufficient volume of data on the physician's or other person's charges is available, would be the median or midpoint of his charges, excluding token and substandard charges as well as exceptional charges on the high side. A significant clustering of charges in the vicinity of the median amount might indicate that a point of such clustering should be taken as the physician's or other person's ''customary'' charge. Use of relative value scales will help in arriving at a decision in such instances.

(c) *Use of relative value scales.* If, for a particular medical procedure or service, the carrier is unable to determine the customary charge on the basis of reliable statistical data (for example, because the carrier does not yet have sufficient data or because the performance of the particular medical procedure or service by the physician or other person is infrequent), the carrier may use appropriate relative value scales to determine the customary charge for such procedure or service in relation to customary charges of the same physician or person for other medical procedures and services.

(d) *Revision of customary charge.* A physician's or other person's customary charge is not necessarily a static amount. Where a physician or other person alters his charges, a revised pattern of charges for his services may develop. Where on the basis of adequate evidence, the carrier finds that the physician or other person furnishing services has changed his charge for a service to the public in general, the customary charge resulting from the revised charge for the service should be recognized as the customary charge in making determinations of reasonable charges for such service when rendered thereafter to supplementary insurance beneficiaries. If the new customary charge is not above the top of the range of prevailing charges (see § 405.504(a)), it should be deemed to be reasonable by the carrier, subject to the provisions of § 405.508.

§ 405.504 Determining prevailing charges.

(a) *Ranges of charges.* (1) In the case of physicians' services furnished beginning January 1, 1987, the prevailing charges for a nonparticipating physician as defined in this paragraph will be no higher than the same level that was set for services furnished during the previous calendar year for a physician who was a participating physician during that year. A nonparticipating physician is a physician who has not entered into an agreement with the Medicare program to accept payment on an assignment-related basis (in accordance with § 424.55 of this chapter)

for all items and services furnished to individuals enrolled under Part B of Medicare during a given calendar year.

(2) No charge for Part B medical or other health services may be considered to be reasonable if it exceeds the higher of:

(i) The prevailing charge for similar services in the same locality in effect on December 31, 1970, provided such prevailing charge had been found acceptable by CMS; or

(ii) The prevailing charge that, on the basis of statistical data and methodology acceptable to CMS, would cover:

(A) 75 percent of the customary charges made for similar services in the same locality during the 12-month period of July 1 through June 30 preceding the fee screen year (January 1 through December 31) in which the service was furnished; or

(B) In the case of services furnished more than 12 months before the beginning of the fee screen year (January 1 through December 31) in which the claim or request for payment is submitted, 75 percent of the customary charges made for similar services in the same locality during the 12 month period of July 1 through June 30 preceding the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is submitted.

(3)(i) In the case of physicians' services, furnished before January 1, 1992, each prevailing charge in each locality may not exceed the prevailing charge determined for the FY ending June 30, 1973 (without reference to the adjustments made in accordance with the economic stabilization program then in effect), except on the basis of appropriate economic index data that demonstrate the higher prevailing charge level is justified by:

(A) Changes in general earnings levels of workers that are attributable to factors other than increases in their productivity; and

(B) changes in expenses of the kind incurred by physicians in office practice. The office-expense component and the earnings component of such index shall be given the relative weights shown in data on self-employed physicians' gross incomes.

Example. The available data indicate the office-expense and earnings components of the index should be given relative weights of 40 percent and 60 percent, respectively, and it is calculated that the aggregate increase in expenses of practice for a particular July through June period was 112 percent over the expenses of practice for calendar year 1971 and the increase in earnings (less increases in workers' productivity was 110 percent over the earnings for calendar year 1971. The allowable increase in any prevailing charge that could be recognized during the next fee screen year would be 110.8 percent ((.40×112)+(.60)×110)=110.8) above the prevailing charge recognized for fiscal year 1973.

(ii)(A) If the increase in the prevailing charge in a locality for a particular physician service resulting from an aggregate increase in customary charges for that service does not exceed the index determined under paragraph (a)(3)(i) of this section, the increase is permitted and any portion of the allowable increase not used is carried forward and is a basis for justifying increases in that prevailing charge in the future. However, if the increase in the prevailing charge exceeds the allowable increase, the increase will be reduced to the allowable amount. Further increases will be justified only to the degree that they do not exceed further rises in the economic index. The prevailing charge for physicians' services furnished during the 15-month period beginning July 1, 1984 may not exceed the prevailing charge for physicians' services in effect for the 12-month period beginning July 1, 1983. The increase in prevailing charges for physicians' services for subsequent fee screen years similarly may not reflect the rise in the economic index that would have otherwise been provided for the period beginning July 1, 1984, and must be treated as having fully provided for the rise in the economic index which would have been otherwise taken into account.

(B) Notwithstanding the provisions of paragraphs (a)(3)(i) and (ii)(A) of this section, the prevailing charge in the case of a physician service in a particular locality determined pursuant to paragraphs (a)(2) and (3)(i) of this section for the fiscal year beginning July 1, 1975, and for any subsequent fee

screen years, if lower than the prevailing charge for the fiscal year ending June 30, 1975, by reason of the application of economic index data, must be raised to such prevailing charge which was in effect for the fiscal year ending June 30, 1975. (If the amount paid on any claim processed by a carrier after the original reasonable charge update for the fiscal year beginning July 1, 1975, and prior to the adjustments required by the preceding sentence, was at least $1 less than the amount due pursuant to the preceding sentence, the difference between the amount previously paid and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously paid and the amount due is less than $1.)

(iii) If, for any reason, a prevailing charge for a service in a locality has no precise counterpart in the carrier's charge data for calendar year 1971 (the data on which the prevailing charge calculations for fiscal year 1973 were based), the limit on the prevailing charge will be estimated, on the basis of data and methodology acceptable to CMS, to seek to produce the effect intended by the economic index criterion. The allowance or reduction of an increase in a prevailing charge for any individual medical item or service may affect the allowance or reduction of an increase in the prevailing charges for other items or services if, for example, the limit on the prevailing charge is estimated, or if the prevailing charges for more than one item or service are established through the use of a relative value schedule and dollar conversion factors.

(b) *Variation in range of prevailing charges.* The range of prevailing charges in a locality may be different for physicians or other persons who engage in a specialty practice or service than for others. Existing differentials in the level of charges between different kinds of practice or service could, in some localities, lead to the development of more than one range of prevailing charges for application by the carrier in its determinations of reasonable charges. Carrier decisions in this respect should be responsive to the existing patterns of charges by physicians and other persons who render covered services, and should establish differentials in the levels of charges between different kinds of practice or service only where in accord with such patterns.

(c) *Re-evaluation and adjustment of prevailing charges.* Determinations of prevailing charges by the carrier are to be re-evaluated and adjusted from time to time on the basis of factual information about the charges made by physicians and other persons to the public in general. This information should be obtained from all possible sources including a carrier's experience with its own programs as well as with the supplementary medical insurance program.

(d) *Computation and issuance of the MEI after CY 1992*—(1) For update years after CY 1992, the MEI is a physician input price index, in which the annual percent changes for the direct-labor price components are adjusted by an annual percent change in a 10-year moving average index of labor productivity in the nonfarm business sector.

(2) The MEI is constructed, using as a base year, CY 1989 weights and annual percent changes in the economic price proxies as shown on the following chart:

MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES

Expense category	1989 weights [1,2] (percent)	Price proxy [3]
Total	100.0	
1. Physician's Own Time (net income, general earnings).	54.2	
a. Wages and Salaries	45.3	Average hourly earnings, total private non-farm.[4]
b. Fringe Benefits	8.8	Employment Cost Index, fringe benefits, private non-farm.[4]

MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES—Continued

Expense category	1989 weights [1,2] (percent)	Price proxy [3]
2. Physician Practice Expense	45.8	
a. Non-physician Employee Compensation	16.3	
(1) Wages and Salaries	13.8	Employment Cost Index, wages and salaries weighted for occupational mix of non-physician employees.[4]
(2) Fringe Benefits	2.5	Employment Cost Index, fringe benefits, white collar.[4]
b. Office Expense	10.3	CPI-U, housing.
c. Medical Materials and Supplies	5.2	PPI, ethical drugs; PPI, surgical appliances and supplies; and CPI-U medical equipment and supplies (equally weighted).
d. Professional Liability Insurance	4.8	CMS survey of change in average liability premiums for $100,000/$300,000 liability coverage among 9 major insurers.
e. Medical Equipment	2.3	PPI, medical instruments and equipment.
f. Other Professional Expense	6.9	
(1) Professional Car	1.4	CPI-U, private transportation.
(2) Other	5.5	CPI-U, all items less food and energy.

[1] Sources: Martin L. Gonzalez, ed.: *Physician Marketplace Statistics, Fall, 1990.* Center for Health Policy Research, Chicago, American Medical Association, 1990; Mark Holoweiko, ''Practice Expenses Take the Leap of the Decade,'' *Medical Economics,* November 12, 1990; and CMS, OACT special study.
[2] Due to rounding, weights may not sum to 100.0%
[3] All price proxies are for *annual* percent changes for the 12 months ending June 30th.
[4] Annual percent change values for Physicians' Own Time and Non-physician Employee Compensation are net of the change in the 10-year moving average of output per man-hour to exclude changes in non-farm business sector labor productivity.

(3) If there is no methodological change, CMS publishes a notice in the FEDERAL REGISTER to announce the annual increase in the MEI before the beginning of the update year to which it applies. If there are changes in the base year weights or price proxies, or if there are any other MEI methodological changes, they are published in the FEDERAL REGISTER with an opportunity for public comment.

[32 FR 12600, Aug. 31, 1967, as amended at 40 FR 25447, June 16, 1975; 42 FR 18275, Apr. 6, 1977. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 4430, Feb. 2, 1978; 47 FR 63274, Dec. 31, 1982; 51 FR 34978, Oct. 1, 1986; 53 FR 6648, Mar. 2, 1988; 57 FR 55912, Nov. 25, 1992]

§ 405.505 Determination of locality.

''Locality'' is the geographical area for which the carrier is to derive the reasonable charges or fee schedule amounts for services or items. Usually, a locality may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a State, or a group of States. It should include a cross section of the population with respect to economic and other characteristics. Where people tend to gravitate toward certain population centers to obtain medical care or service, localities may be recognized on a basis constituting medical services areas (interstate or otherwise), comparable in concept to ''trade areas.'' Localities may differ in population density, economic level, and other major factors affecting charges for services. Carriers therefore shall delineate localities on the basis of their knowledge of local conditions. However, distinctions between localities are not to be so finely made that a locality includes only a very limited geographic area whose population has distinctly similar income characteristics (e.g., a very rich or very poor neighborhood within a city).

[57 FR 27305, June 18, 1992]

§ 405.506 Charges higher than customary or prevailing charges or lowest charge levels.

A charge which exceeds the customary charge of the physician or other person who rendered the medical or other health service, or the prevailing charge in the locality, or an applicable lowest charge level may be found to be reasonable, but only where there are unusual circumstances, or medical complications requiring additional time, effort or expense which support an additional charge, and only if it is acceptable medical or medical service practice in the locality to make an extra charge in such cases. The

mere fact that the physician's or other person's customary charge is higher than prevailing would not justify a determination that it is reasonable.

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331; 86 Stat. 1395, 1454; (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978]

§ 405.507 Illustrations of the application of the criteria for determining reasonable charges.

The following examples illustrate how the general criteria on customary charges and prevailing charges might be applied in determining reasonable charges under the supplementary medical insurance program. Basically, these examples demonstrate that, except where the actual charge is less, reasonable charges will reflect current customary charges of the particular physician or other person within the ranges of the current prevailing charges in the locality for that type and level of service:

The prevailing charge for a specific medical procedure ranges from $80 to $100 in a certain locality.

Doctor A's bill is for $75 although he customarily charges $80 for the procedure.

Doctor B's bill is his customary charge of $85

Doctor C's bill is his customary charge of $125

Doctor D's bill is for $100, although he customarily charges $80, and there are no special circumstances in the case.

The reasonable charge for Doctor A would be limited to $75 since under the law the reasonable charge cannot exceed the actual charge, even if it is lower than his customary charge and below the prevailing charges for the locality.

The reasonable charge for Doctor B would be $85, because it is his customary charge and it falls within the range of prevailing charges for that locality.

The reasonable charge for Doctor C could not be more than $100, the top of the range of prevailing charges.

The reasonable charge for Doctor D would be $80, because that is his customary charge. Even though his actual charge of $100 falls within the range of prevailing charges, the reasonable charge cannot exceed his customary charge in the absence of special circumstances.

§ 405.508 Determination of comparable circumstances; limitation.

(a) *Application of limitation*. The carrier may not in any case make a determination of reasonable charge which would be higher than the charge upon which it would base payment to its own policyholders for a comparable service in comparable circumstances. The charge upon which it would base payment, however, does not necessarily mean the amount the carrier would be obligated to pay. Under certain circumstances, some carriers pay amounts on behalf of individuals who are their policyholders, which are below the customary charges of physicians or other persons to other individuals. Payment under the supplementary medical insurance program would not be limited to these lower amounts.

(b) *When comparability exists*. ''Comparable circumstances,'' as used in the Act and this subpart, refers to the circumstances under which services are rendered to individuals and the nature of the carrier's health insurance programs and the method it uses to determine the amounts of payments under these programs. Generally, comparability would exist where:

(1) The carrier bases payment under its program on the customary charges, as presently constituted, of physicians or other persons and on current prevailing charges in a locality, and

(2) The determination does not preclude recognition of factors such as speciality status and unusual circumstances which affect the amount charged for a service.

(c) *Responsibility for determining comparability*. Responsibility for determining whether or not a carrier's program has comparability will in the first instance fall upon the carrier in reporting pertinent information about its programs to the Centers for Medicare & Medicaid Services. When the pertinent information has been reported, the Centers for Medicare & Medicaid Services will advise the carrier whether any of its programs have comparability.

§ 405.509 Determining the inflation-indexed charge.

(a) *Definition.* For purposes of this section, *inflation-indexed charge* means the lowest of the fee screens used to determine reasonable charges (as determined in § 405.503 for the customary charge, § 405.504 for the prevailing charge, this section for the inflation-indexed charge, and § 405.511 for the lowest charge level) for services, supplies, and equipment reimbursed on a reasonable charge basis (excluding physicians' services), that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor, as described in paragraph (b) of this section.

(b) *Application of inflation adjustment factor to determine inflation-indexed charge.* (1) For fee screen years beginning on or after January 1, 1987, the inflation-indexed charge is determined by updating the fee screen used to determine the reasonable charges in effect on December 31 of the previous fee screen year by application of an inflation adjustment factor, that is, the annual change in the level of the consumer price index for all urban consumers, as compiled by the Bureau of Labor Statistics, for the 12-month period ending on June 30 of each year.

(2) For services, supplies, and equipment furnished from October 1, 1985 through December 31, 1986 the inflation adjustment factor is zero.

(c) The inflation-indexed charge does not apply to any services, supplies, or equipment furnished after December 31, 1991, that are covered under or limited by the fee schedule for physicians' services established under section 1848 of the Act and part 415 of this chapter. These services are subject to the Medicare Economic Index described in § 415.30 of this chapter.

[51 FR 34979, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986, as amended at 56 FR 59621, Nov. 25, 1991]

§ 405.511 Reasonable charges for medical services, supplies, and equipment.

(a) *General rule.* (1) A charge for any medical service, supply, or equipment (including equipment servicing) that in the judgment of CMS generally does not vary significantly in quality from one supplier to another (and that is identified by a notice published in the FEDERAL REGISTER) may not be considered reasonable if it exceeds:

(i) The customary charge of the supplier (see § 405.503);

(ii) The prevailing charge in the locality (see § 405.504);

(iii) The charge applicable for a comparable service and under comparable circumstances to the policyholders or subscribers of the carrier (see § 405.508);

(iv) The lowest charge level at which the item or service is widely and consistently available in the locality (see paragraph (c) of this section); or

(v) The inflation-indexed charge, as determined under § 405.509, in the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services).

(2) In the case of laboratory services, paragraph (a)(1) of this section is applicable to services furnished by physicians in their offices, by independent laboratories (see § 405.1310(a)) and to services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital. Allowance of additional charges exceeding the lowest charge level can be approved by the carrier on the basis of unusual circumstances or medical complications in accordance with § 405.506.

(b) *Public notice of items and services subject to the lowest charge level rule.* Before the Secretary determines that lowest charge levels should be established for an item or service, notice of the proposed determination will be published with an opportunity for public comment. The descriptions or specifications of items or services in the notice will be in sufficient detail to permit a determination that items or services conforming to the descriptions will not vary significantly in quality.

(c) *Calculating the lowest charge level.* The lowest charge level at which an item or service is widely and consistently available in a locality is calculated by the carrier in accordance with instructions from CMS as follows:

(1) *For items or services furnished on or before December 31, 1986.*

(i) A lowest charge level is calculated for each identified item or service in January and July of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the second calendar quarter preceding the determination date. Accordingly, the January calculations will be based on charges for the July through September quarter of the previous calendar year, and the July calculations will be based on charges for the January through March quarter of the same calendar year.

(2) *For items or services furnished on or after January 1, 1987.*

(i) A lowest charge level is calculated for each identified item or service in January of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the 3-month period of July 1 through September 30 preceding the fee screen year (January 1 through December 31) for which the item or service was furnished.

(3) *Lowest charge levels for laboratory services.* In setting lowest charge levels for laboratory services, the carrier will consider only charges made for laboratory services performed by physicians in their offices, by independent laboratories which meet coverage requirements, and for services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital.

(d) *Locality.* Subject to the approval of the Secretary, the carrier may designate its entire service area as the locality for purposes of this section, or may otherwise modify the localities used for calculating prevailing charges. (The modified locality for an item or service will also be used for calculating the prevailing charge for that item or service.)

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331, 86 Stat. 1395, 1454 (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978, as amended at 50 FR 40174, Oct. 1, 1985; 51 FR 34979, Oct. 1, 1986]

§405.512 Carriers' procedural terminology and coding systems.

(a) *General.* Procedural terminology and coding systems are designed to provide physicians and third party payers with a common language that accurately describes the kinds and levels of services provided and that can serve as a basis for coverage and payment determinations.

(b) *Modification of terminology and/or coding systems.* A carrier that wishes to modify its system of procedural terminology and coding shall submit its request to the Centers for Medicare & Medicaid Services with all pertinent data and information for approval before the revision is implemented. The Centers for Medicare & Medicaid Services will evaluate the proposal in the light of the guidelines specified in paragraph (c) of this section and such other considerations as may be pertinent, and consult with the Assistant Secretary for Health. The Centers for Medicare & Medicaid Services will approve such a revision if it determines that the potential advantages of the proposed new system, outweigh the disadvantages.

(c) *Guidelines.* The following considerations and guidelines are taken into account in evaluating a carrier's proposal to change its system of procedural terminology and coding:

(1) The rationale for converting to the new terminology and coding;

(2) The estimated short-run and long-run impact on the cost of the health insurance program, other medical care costs, administrative expenses, and the reliability of the estimates;

(3) The degree to which the conversion to the proposed new terminology and coding can be accomplished in a way that permits full implementation of the reasonable charge criteria in accordance with the provisions of this subpart;

(4) The degree to which the proposed new terminology and coding are accepted by physicians in the carrier's area (physician acceptance is assumed only if a majority of the Medicare and non-Medicare bills and claims completed by physicians in the area and submitted to the carrier can reasonably be expected to utilize the proposed new terminology and coding);

(5) The extent to which the proposed new terminology and coding system is used by the carrier in its non-Medicare business;

(6) The clarity with which the proposed system defines its terminology and whether the system lends itself to:

(i) Accurate determinations of coverage;

(ii) Proper assessment of the appropriate level of payment; and

(iii) Meeting the carrier's or Professional Standards Review Organizations' review needs and such other review needs as may be appropriate;

(7) Compatibility of the new terminology and coding system with other systems that the carrier and other carriers may utilize in the administration of the Medicare program—e.g., its compatibility with systems and statistical requirements and with the historical data in the carrier's processing system; and

(8) Compatibility of the proposed system with the carriers methods for determining payment under the fee schedule for physicians' services for services which are identified by a single element of terminology but which may vary in content.

[40 FR 7639, Feb. 21, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 10298, Mar. 4, 1994]

§ 405.515 Reimbursement for clinical laboratory services billed by physicians.

This section implements section 1842(h) of the Social Security Act, which places a limitation on reimbursement for markups on clinical laboratory services billed by physicians. If a physician's bill, or a request for payment for a physician's services, includes a charge for a laboratory test for which payment may be made under this part, the amount payable with respect to the test shall be determined as follows (subject to the coinsurance and deductible provisions at §§ 410.152 and 410.160 of this chapter):

(a) If the bill or request for payment indicates that the test was personally performed or supervised either by the physician who submitted the bill (or for whose services the request for payment was made), or by another physician with whom that physician shares his or her practice, the payment will be based on the physician's reasonable charge for the test (as determined in accordance with § 405.502).

(b) If the bill or request for payment indicates that the test was performed by an outside laboratory, and identifies both the laboratory and the amount the laboratory charged, payment for the test will be based on the lower of—

(1) The laboratory's reasonable charge for the service (as determined in accordance with § 405.502), or

(2) The amount that the laboratory charged the physician for the service.

(c) If the bill or request for payment does not indicate that the conditions specified in paragraph (a) of this section were met, and does not identify both the laboratory and the amount the laboratory charged, payment will be based on the lowest charge at which the carrier estimates the test could have been secured from a laboratory serving the physician's locality. The carrier will estimate this lowest amount twice a year by (i) obtaining lists of charges laboratories make to physicians from as many commercial laboratories serving the carrier's area as possible (including laboratories in other States from which tests may be obtained by physicians in the carrier's service area) and (ii) establishing a schedule of lowest prices based on this information. The carrier will take into consideration specific circumstances, such as a need for emergency services that may be costlier than routine services, in making the estimate in a particular case. However, in no case may this estimate be higher than the lowest customary charge for commercial laboratories, or when applicable to the laboratory service, the lowest charge level determined in accordance with § 405.511, in the carrier's service area.

(d) When a physician bills, in accordance with paragraph (b) or (c) of this section, for a laboratory test and indicates that it was performed by an independent laboratory, a nominal payment will also be made to the physician for collecting, handling, and shipping the specimen to the laboratory, if the physician bills for such a service.

[46 FR 42672, Aug. 24, 1981, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.517 Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.

(a) *Applicability*. (1) *Payment for drugs and biologicals before January 1, 2004*. Payment for a drug or biological that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies include a drug or biological furnished incident to a physician's service, a drug or biological furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter, and a drug or biological furnished as part of the durable medical equipment benefit.

(2) *Payment for drugs and biologicals on or after January 1, 2004*. Effective January 1, 2004, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with Part 414, subpart I of this chapter.

(3) *Payment for drugs and biologicals on or after January 1, 2005*. Effective January 1, 2005, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with part 414, subpart K of this chapter.

(b) *Methodology*. Payment for a drug or biological described in paragraph (a) of this section is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological.

(c) *Multiple-source drugs*. For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological.

[63 FR 58905, Nov. 2, 1998, as amended at 69 FR 1116, Jan. 7, 2004; 69 FR 66420, Nov. 15, 2004]

§ 405.520 Payment for a physician assistant's, nurse practitioner's, and clinical nurse specialists' services and services furnished incident to their professional services.

(a) *General rule*. A physician assistant's, nurse practitioner's, and clinical nurse specialists' services, and services and supplies furnished incident to their professional services, are paid in accordance with the physician fee schedule. The payment for a physician assistants' services may not exceed the limits at § 414.52 of this chapter. The payment for a nurse practitioners' and clinical nurse specialists' services may not exceed the limits at § 414.56 of this chapter.

(b) *Requirements*. Medicare payment is made only if all claims for payment are made on an assignment-related basis in accordance with § 424.55 of this chapter, that sets forth, respectively, the conditions for coverage of physician assistants' services, nurse practitioners' services and clinical nurse specialists' services, and services and supplies furnished incident to their professional services.

(c) *Civil money penalties*. Any person or entity who knowingly and willingly bills a Medicare beneficiary amounts in excess of the appropriate coinsurance and deductible is subject to a civil money penalty as described in §§ 402.1(c)(11), 402.105(d)(2)(viii), and 402.107(b)(8) of this chapter.

[63 FR 58905, Nov. 2, 1998, as amended at 66 FR 49547, Sept. 28, 2001]

§ 405.534 Limitation on payment for screening mammography services.

The provisions in paragraphs (a), (b), and (c) of this section apply for services provided from January 1, 1991 until December 31, 2001. Screening mammography services provided after December 31, 2001 are paid under the physician fee schedule in accordance with § 414.2 of this chapter.

(a) *Basis and scope*. This section implements section 1834(c) of the Act by establishing a limit on payment for screening mammography examinations. There are three categories of billing for screening mammography services. Those categories and the payment limitations on each are set forth

in paragraphs (b) through (d) of this section.

(b) *Global or complete service billing representing both the professional and technical components of the procedure.* If a fee is billed for a global service, the amount of payment subject to the deductible is equal to 80 percent of the least of the following:

(1) The actual charge for the service.

(2) The amount established for the global procedure for a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at part 414, subpart A.

(3) The payment limit for the procedure. For screening mammography services furnished in CY 1994, the payment limit is $59.63. On January 1 of each subsequent year, the payment limit is updated by the percentage increase in the Medicare Economic Index (MEI) and reflects the relationship between the relative value units for the professional and technical components of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(c) *Professional component billing representing only the physician's interpretation for the procedure.* If the professional component of screening mammography services is billed separately, the amount of payment for that professional component, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the professional component of the service.

(2) The amount established for the professional component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The professional component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

(d) *Technical component billing representing other resources involved in furnishing the procedure.* If the technical component of screening mammography services is billed separately, the amount of payment, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the technical component of the service.

(2) The amount established for the technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The technical component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

[55 FR 53521, Dec. 31, 1990, as amended at 59 FR 49833, Sept. 30, 1994; 66 FR 55328, Nov. 1, 2001]

§ 405.535 Special rule for nonparticipating physicians and suppliers furnishing screening mammography services before January 1, 2002.

The provisions in this section apply for screening mammography services provided from January 1, 1991 until December 31, 2001. Screening mammography services provided after December 31, 2001 are physician services pursuant to § 414.2 of this chapter paid under the physician fee schedule. If screening mammography services are furnished to a beneficiary by a nonparticipating physician or supplier that does not accept assignment, a limiting charge applies to the charges billed to the beneficiary. The limiting charge is the lesser of the following:

(a) 115 percent of the payment limit set forth in § 405.534(b)(3), (c)(3), and (d)(3) (limitations on the global service, professional component, and technical component of screening mammography services, respectively).

(b) The limiting charge for the global service, professional component, and technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at § 414.48(b) of this chapter.

[59 FR 49833, Sept. 30, 1994, as amended at 62 FR 59098, Oct. 31, 1997; 66 FR 55328, Nov. 1, 2001]

Subpart F [Reserved]

Subpart G—Reconsiderations and Appeals Under Medicare Part A

AUTHORITY: Secs. 1102, 1155, 1869(b), 1871, 1872, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c–4, 1395ff(b), 1395hh, 1395ii, and 1395pp).

SOURCE: 37 FR 5814, Mar. 22, 1972, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.701 Basis, purpose and definitions.

(a) This subpart implements section 1869 of the Social Security Act. Section 1869(a) provides that the Secretary will make determinations about the following matters, and section 1869(b) provides for a hearing for an individual who is dissatisfied with the Secretary's determination as to:

(1) Whether the individual is entitled to hospital insurance (part A) or supplementary medical insurance (part B) under title XVIII of the Act; or

(2) The amount payable under hospital insurance.

(b) This subpart establishes the procedures governing initial determinations, reconsidered determinations, hearings, and final agency review, and the reopening of determinations and decisions that are applicable to matters arising under paragraph (a) of this section.

(c) Subparts J and R of 20 CFR part 404 (dealing with determinations, the administrative review process and representation of parties) are also applicable to matters arising under paragraph (a) of this section, except to the extent that specific provisions are contained in this subpart.

(d) *Definitions.* As used in subpart G of this part, the term—

Appellant designates the beneficiary, provider or other person or entity that has filed an appeal concerning a particular determination of benefits under Medicare part A. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Common issues of law and fact, with respect to the aggregation of claims by two or more appellants to meet the minimum amount in controversy needed for a hearing, occurs when the claims sought to be aggregated are denied or reduced for similar reasons and arise from a similar fact pattern material to the reason the claims are denied.

Delivery of similar or related services, with respect to the aggregation of claims by two or more provider appellants to meet the minimum amount in controversy needed for a hearing, means like or coordinated services or items provided to the same beneficiary by the appellants.

[55 FR 11020, Mar. 26, 1990, as amended at 59 FR 12181, Mar. 16, 1994]

§ 405.702 Notice of initial determination.

After a request for payment under part A of title XVIII of the Act is filed with the intermediary by or on behalf of the individual who received inpatient hospital services, extended care services, or home health services, and the intermediary has ascertained whether the items and services furnished are covered under part A of title XVIII, and where appropriate, ascertained and made payment of amounts due or has ascertained that no payments were due, the individual will be notified in writing of the initial determination in his case. In addition, if the items or services furnished such individual are not covered under part A of title XVIII by reason of § 411.15(g) or § 411.15(k) and payment may not be made for such items or services under § 411.400 only because the requirements of § 411.400(a)(2) are not met, the provider of services which furnished such items or services will be notified in writing of the initial determination in such individual's case. These notices shall be mailed to the individual and the provider of services at their last known addresses and shall state in detail the basis for the determination. Such written notices shall also inform the individual and the provider of services of their right to reconsideration of the determination if they are dissatisfied with the determination.

[55 FR 11020, Mar. 26, 1990]

§ 405.704 Actions which are initial determinations.

(a) *Applications and entitlement of individuals.* An initial determination with respect to an individual includes the following—

(1) A determination with respect to entitlement to hospital insurance or supplementary medical insurance;

(2) A disallowance of an individual's application for entitlement to hospital or supplementary medical insurance, if the individual fails to submit evidence

requested by SSA to support the application. (SSA will specify in the initial determination the conditions of entitlement that the applicant failed to establish by not submitting the requested evidence);

(3) A denial of a request for withdrawal of an application for hospital or supplementary medical insurance;

(4) A denial of a request for cancellation of a ''request for withdrawal''; and

(5) A determination as to whether an individual, previously determined to be entitled to hospital or supplementary medical insurance, is no longer entitled to such benefits, including a determination based on nonpayment of premiums.

(b) *Requests for payment by or on behalf of individuals.* An initial determination with respect to an individual includes any determination made on the basis of a request for payment by or on behalf of the individual under part A of Medicare, including a determination with respect to:

(1) The coverage of items and services furnished;

(2) The amount of an applicable deductible;

(3) The application of the coinsurance feature;

(4) The number of days of inpatient hospital benefits utilized during a spell of illness or for purposes of the inpatient psychiatric hospital 190-day lifetime maximum;

(5) The number of days of the 60-day lifetime reserve utilized for inpatient hospital coverage;

(6) The number of days of posthospital extended care benefits utilized;

(7) The number of home health visits utilized;

(8) The physician certification requirement;

(9) The request for payment requirement;

(10) The beginning and ending of a spell of illness, including a determination made under the presumptions established under § 409.60(c)(2) of this chapter, as specified in § 409.60(c)(4) of this chapter.

(11) The medical necessity of services (See parts 466 and 473 of this chapter for provisions pertaining to initial and reconsidered determinations made by a QIO);

(12) When services are excluded from coverage as custodial care (§ 411.15(g)) or as not reasonable and necessary (§ 411.15(k)), whether the individual or the provider of services who furnished the services, or both, knew or could reasonably have been expected to know that the services were excluded from coverage (see § 411.402);

(13) Any other issues having a present or potential effect on the amount of benefits to be paid under part A of Medicare, including a determination as to whether there has been an overpayment or underpayment of benefits paid under part A, and if so, the amount thereof; and

(14) Whether a waiver of adjustment or recovery under sections 1870 (b) and (c) of the Act is appropriate when an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1814(e) of the Act) has been made with respect to an individual.

(c) *Initial determination with respect to a provider of services.* An initial determination with respect to a provider of services shall be a determination made on the basis of a request for payment filed by the provider under part A of Medicare on behalf of an individual who was furnished items or services by the provider, but only if the determination involves the following:

(1) A finding by the intermediary that such items or services are not covered by reason of § 411.15(g) or § 411.15(k); and

(2) A finding by the intermediary that either such individual or such provider of services, or both, knew or could reasonably have been expected to know that such items or services were excluded from coverage under the program.

[55 FR 11020, Mar. 26, 1990]

§ 405.705 Actions which are not initial determinations.

An initial determination under Part A of Medicare does not include determinations relating to:

(a) The reasonable cost of items or services furnished under Part A of Medicare;

(b) Whether an institution or agency meets the conditions for participation in the program;

(c) Whether an individual is qualified for use of the expedited appeals process as provided in § 405.718;

(d) An action regarding compromise of a claim arising under the Medicare program, or termination or suspension of collection action on such a claim under the Federal Claims Collection Act of 1966 (31 U.S.C. 3711). See 20 CFR 404.515 for overpayment claims against an individual, § 405.376 for overpayment claims against a provider, physician or other supplier, and § 408.110 for claims concerning unpaid Medicare premiums;

(e) The transfer or discharge of residents of skilled nursing facilities in accordance with § 483.12 of this chapter; or

(f) The preadmission screening and annual resident review processes required by part 483 subparts C and E of this chapter.

[45 FR 73932, Nov. 7, 1980; 46 FR 24565, May 1, 1981, as amended at 52 FR 22454, June 12, 1987; 52 FR 48123, Dec. 18, 1987; 57 FR 56504, Nov. 30, 1992; 61 FR 63749, Dec. 2, 1996]

§ 405.706 Decisions of utilization review committees.

(a) *General rule.* A decision of a utilization review committee is a medical determination by a staff committee of the provider or a group similarly composed and does not constitute a determination by the Secretary within the meaning of section 1869 of the Act. The decision of a utilization review committee may be considered by CMS along with other pertinent medical evidence in determining whether or not an individual has the right to have payment made under Part A of title XVIII.

(b) *Applicability under the prospective payment system.* CMS may consider utilization review committee decisions related to inpatient hospital services paid for under the prospective payment system (see part 412 of this chapter) only as those decisions concern:

(1) The appropriateness of admissions resulting in payments under subparts D, E and G of part 412 of this chapter.

(2) The covered days of care involved in determinations of outlier payments under § 412.80(a)(1)(i) of this chapter; and

(3) The necessity of professional services furnished in high cost outliers under § 412.80(a)(1)(ii) of this chapter.

[48 FR 39831, Sept. 1, 1983]

§ 405.708 Effect of initial determination.

(a) The initial determination under § 405.704 (a) or (b) shall be binding upon the individual on whose behalf payment under part A has been requested or, if such individual is deceased, upon the representative of such individual's estate, unless it is reconsidered in accordance with §§ 405.710 through 405.717 or revised in accordance with § 405.750. Such individual (or the representative of such individual's estate if the individual is deceased) shall be the party to such initial determination.

(b) The initial determination under § 405.704(c) shall be binding upon the provider of services unless it is reconsidered in accordance with §§ 405.710 through 405.717 or revised in accordance with § 405.750. Such provider of services shall be the party to such initial determination.

[55 FR 11021, Mar. 26, 1990, as amended at 62 FR 25855, May 12, 1997]

§ 405.710 Right to reconsideration.

(a) An individual who is a party to an initial determination, as specified in § 405.704 (a) and (b), (or if such individual is deceased, the representative of such individual's estate) and who is dissatisfied with the initial determination may request a reconsideration of such determination in accordance with § 405.711 regardless of the amount in controversy.

(b) A provider of services who is a party to an initial determination (as specified in § 405.704(c)) and who is dissatisfied with such initial determination may request a reconsideration of such determination in accordance with § 405.711, regardless of the amount in controversy, but only if the individual on whose behalf the request for payment was made has indicated in writing that he does not intend to request reconsideration of the intermediary's initial determination on such request for payment, or if the intermediary has made a finding (see § 405.704(c)) that such individual did not know or could

not reasonably have been expected to know that the expenses incurred for the items or services for which such request for payment was made were not reimbursable by reason of § 411.15(g) or § 411.15(k).

[55 FR 11021, Mar. 26, 1990]

§ 405.711 Time and place of filing request for reconsideration.

The request for reconsideration shall be made in writing and filed at an office of the SSA or the CMS or, in the case of a qualified railroad retirement beneficiary (see 20 CFR 404.368) filed at an office of the Railroad Retirement Board, within 60 days after the date of receipt of notice of initial determination, unless such time is extended as provided in § 405.712. A request for reconsideration which is filed with the intermediary which received the request for payment submitted on behalf of the individual is considered to have been filed with the CMS as of the date it is filed with the intermediary. For purposes of this section, the date of receipt of notice of the initial determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[41 FR 47917, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.712 Extension of time to request reconsideration.

If a party to an initial determination desires to file a request for reconsideration after the time for filing such request in accordance with § 405.711 has passed, such party may file a petition with the SSA or the CMS or, in the case of a qualified railroad retirement beneficiary, with the Railroad Retirement Board, for an extension of time for the filing of such request. Such petition shall be in writing and shall state the reasons why the request for reconsideration was not filed within the required time. For good cause shown, the CMS may extend the time for filing the request for reconsideration.

[37 FR 5814, Mar. 22, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.714 Withdrawal of request for reconsideration.

A request for reconsideration may be withdrawn by the party to the initial determination who filed the request or by his representative provided that the withdrawal is made in writing and filed at an office of the SSA or the CMS or, in the case of a qualified railroad retirement beneficiary, with the Railroad Retirement Board prior to the date of the mailing of the notice of reconsidered determination. A withdrawal filed with the intermediary which received the request for payment submitted on behalf of the individual is considered to have been filed with the CMS as of the date it is filed with the intermediary.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.715 Reconsidered determination.

(a) In reconsidering an initial determination, the CMS shall review such initial determination, the evidence and findings upon which such determination was based, and any additional evidence submitted to the SSA or the CMS or otherwise obtained by the intermediary or the CMS; and shall make a determination affirming or revising, in whole or in part, such initial determination.

(b) If the request for reconsideration is filed by an individual with respect to an initial determination specified in § 405.704(b)(12), the provider of services who furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto. If pursuant to § 405.710(b) a request for reconsideration is filed by a provider of services with respect to an individual determination under § 405.704(c), the individual who was furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto.

[55 FR 11021, Mar. 26, 1990, as amended at 62 FR 25855, May 12, 1997]

§ 405.716 Notice of reconsidered determination.

Written notice of the reconsidered determination shall be mailed by the CMS to the parties and their representatives at their last known addresses.

Such notice shall state the specific reasons for the reconsidered determination and shall advise the parties of their right to a hearing if the amount in controversy is $100 or more, or, if appropriate, advise them of the requirements for use of the expedited appeals process (see § 405.718).

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.717 Effect of a reconsidered determination.

The reconsidered determination is binding upon all parties unless—

(a) A request for a hearing is filed with SSA or CMS within 60 days after the date of receipt of notice of the reconsidered determination by the parties (for purposes of this section, the date of receipt of notice of the reconsidered determination is presumed to be 5 days after the date of the notice, unless it is shown that the notice was received earlier or later); or

(b) The reconsidered determination is revised in accordance with § 405.750; or

(c) The expedited appeals process is used in accordance with § 405.718.

[62 FR 25852, May 12, 1997]

§ 405.718 Expedited appeals process.

(a) *Conditions for use of expedited appeals process (EAP).* A party may use the EAP to request court review in place of an administrative law judge (ALJ) hearing or Departmental Appeals Board (DAB) review if the following conditions are met:

(1) CMS has made a reconsideration determination; an ALJ has made a hearing decision; or DAB review has been requested, but a final decision has not been issued.

(2) The filing entity is a party referred to in § 405.718(d).

(3) The party has filed a request for an ALJ hearing in accordance with § 405.722, or DAB review in accordance with 20 CFR 404.968.

(4) The amount remaining in controversy is $1,000 or more.

(5) If there is more than one party to the reconsideration determination or hearing decision, each party concurs, in writing, with the request for the EAP.

(b) *Content of the request for EAP.* The request for the EAP:

(1) Alleges that there are no material issues of fact in dispute; and

(2) Asserts that the only factor precluding a decision favorable to the party is a statutory provision that is unconstitutional or a regulation, national coverage decision under section 1862(a)(1) of the Act, or CMS Ruling that is invalid.

(c) *Place and time for requesting an EAP*—(1) *Place for filing request.* The person must file a written request—

(i) At an office of SSA or CMS; or

(ii) If the person is in the Philippines, at the Veterans Administration Regional Office or with an ALJ; or

(iii) If the person is a qualified railroad retirement beneficiary, at an office of the Railroad Retirement Board.

(2) *Time of filing request.* The party may file a request for the EAP—

(i) If the party has requested a hearing, at any time prior to receipt of the notice of the ALJ's decision;

(ii) Within 60 days after the date of receipt of notice of the ALJ's decision or dismissal, unless the time is extended in accordance with the standards set out in 20 CFR 404.925(c). For purposes of this section, the date of receipt of the notice is presumed to be 5 days after the date on the notice, unless it is shown that the notice was received later; or

(iii) If the party has requested DAB review, at any time prior to receipt of notice of the Board's decision.

(d) *Parties to the EAP.* The parties to the EAP are the persons who were parties to the reconsideration determination and, if appropriate, to the hearing.

(e) *Determination on request for EAP.* (1) For EAP requests initiated at the ALJ level, an ALJ determines whether all conditions of paragraphs (a) and (b) of this section are met.

(2) If a hearing decision has been issued, the DAB determines whether all conditions of paragraphs (a) and (b) of this section are met.

(f) *ALJ or DAB certification for the EAP.* If the party meets the requirements for the EAP, the ALJ or the DAB, as appropriate, certifies the case in writing stating that:

(1) The facts involved in the claim are not in dispute;

(2) Except as indicated in paragraph (f)(3) of this section, CMS's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision or the validity of a regulation, CMS Ruling, or national coverage decision based on section 1862(a)(1) of the Act.

(4) Except for the provision challenged, the right(s) of the party is established; and

(5) The determination or decision made by the ALJ or DAB is final for purposes of seeking judicial review.

(g) *Effect of ALJ or DAB certification.* (1) Following the issuance of the certification described in paragraph (f) of this section, the party waives completion of the remaining steps of the administrative appeals process.

(2) The 60-day period for filing a civil suit in a Federal district court begins on the date of receipt of the ALJ or DAB certification.

(h) *Effect of a request for EAP that does not result in certification.* If a request for the EAP does not meet all the conditions for use of the process, the ALJ or DAB so advises the party and treats the request as a request for hearing or DAB review, as appropriate.

[62 FR 25852, May 12, 1997]

§ 405.720 Hearing; right to hearing.

A person has a right to a hearing regarding any initial determination made under § 405.704 if:

(a) Such initial determination has been reconsidered by the CMS;

(b) Such person was a party to the reconsidered determination;

(c) Such person or his representative has filed a written request for a hearing in accordance with the procedure described in § 405.722; and

(d) The amount in controversy is $100 or more.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.722 Time and place of filing request for a hearing.

The request for a hearing shall be made in writing and filed at an office of the SSA or the CMS or with a ALJ, or, in the case of a qualified railroad retirement beneficiary, at an office of the Railroad Retirement Board. Such request must be filed within 60 days after the date of receipt of notice of the reconsidered determination by such individual, except where the time is extended as provided in 20 CFR 404.933(c). For purposes of this section, the date of receipt of notice of the reconsidered determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[45 FR 73933, Nov. 7, 1980, as amended at 62 FR 25855, May 12, 1997]

§ 405.724 Departmental Appeals Board (DAB) review.

Regulations beginning at 20 CFR 404.967 regarding SSA Appeals Council Review are also applicable to DAB review of matters addressed by this subpart.

[62 FR 25852, May 12, 1997]

§ 405.730 Court review.

(a) To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a Departmental Appeals Board (DAB) decision or an ALJ decision if the DAB does not review the ALJ decision, may obtain a court review if the amount remaining in controversy is $1,000 or more. A party may obtain court review by filing a civil action in a district court of the United States in accordance with the provisions of section 205(g) of the Act. The filing procedure is set forth at 20 CFR 422.210.

(b) A party to a reconsidered determination or an ALJ hearing decision may obtain a court review if the amount in controversy is $1,000 or more, and he or she requests and meets the conditions for the expedited appeals process set forth in § 405.718.

[62 FR 25852, May 12, 1997]

§ 405.732 Review of a national coverage determination (NCD).

(a) *General rule.* (1) An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under title XVIII of the Act.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service

covered under title XVIII or a determination for the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.

(4) An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.

(b) *Review by ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

(c) *Review by Court.* For initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. In these cases, the court may not invalidate an NCD except upon review of the supplemental record.

[68 FR 63715, Nov. 7, 2003]

§ 405.740 Principles for determining the amount in controversy.

(a) *Individual appellants.* For the purpose of determining whether an individual appellant meets the minimum amount in controversy needed for a hearing ($100), the following rules apply:

(1) The amount in controversy is computed as the actual amount charged the individual for the items and services in question, less any amount for which payment has been made by the intermediary and less any deductible and coinsurance amounts applicable in the particular case.

(2) A single beneficiary may aggregate claims from two or more providers to meet the $100 hearing threshold and a single provider may aggregate claims for services provided to one or more beneficiaries to meet the $100 hearing threshold.

(3) In either of the circumstances specified in paragraph (a)(2) of this section, two or more claims may be aggregated by an individual appellant only if the claims have previously been reconsidered and a request for hearing has been made within 60 days after receipt of the reconsideration determination(s).

(4) When requesting a hearing, the appellant must specify in his or her appeal request the specific claims to be aggregated.

(b) *Two or more appellants.* As specified below, under section 1869(b)(2) of the Act, two or more appellants may aggregate their claims together to meet the minimum amount in controversy needed for a hearing ($100). The right to aggregate under this statutory provision applies to claims for items and services furnished on or after January 1, 1987.

(1) The aggregate amount in controversy is computed as the actual amount charged the individual(s) for the items and services in question, less any amount for which payment has been made by the intermediary and less any deductible and coinsurance amounts applicable in the particular case.

(2) In determining the amount in controversy, two or more appellants may aggregate their claims together under the following circumstances:

(i) Two or more beneficiaries may combine claims representing services from the same or different provider(s) if the claims involve common issues of law and fact;

(ii) Two or more providers may combine their claims if the claims involve the delivery of similar or related services to the same beneficiary; or

(iii) Two or more providers may combine their claims if the claims involve common issues of law and fact with respect to services furnished to two or more beneficiaries.

(iv) In any of the circumstances specified in paragraphs (b)(2)(i) through (b)(2)(iii) of this section, the claims may be aggregated only if the claims have previously been reconsidered and a request for hearing has been made within 60 days after receipt of the reconsideration determination(s). Moreover, in the request for hearing, the appellants must specify the claims that they seek to aggregate.

(c) The determination as to whether the amount in controversy is $100 or more is made by the administrative law judge (ALJ).

(d) In determining the amount in controversy under paragraph (b) of this section, the ALJ also makes the determination as to what constitutes ''similar or related services'' or ''common issues of law and fact.''

(e) When a civil action is filed by either an individual appellant or two or more appellants, the Secretary may assert that the aggregation principles contained in this subpart may be applied to determine the amount in controversy for judicial review ($1000).

(f) Notwithstanding the provisions of paragraphs (a)(1) and (b)(1) of this section, when payment is made for certain excluded services under § 411.400 of this chapter or the liability of the beneficiary for those services is limited under § 411.402 of this chapter, the amount in controversy is computed as the amount that would have been charged the beneficiary for the items or services in question, less any deductible and coinsurance amounts applicable in the particular case, had such expenses not been paid pursuant to § 411.400 of this chapter or had such liability not been limited pursuant to § 411.402 of this chapter.

(g) Under this subpart, an appellant may not combine part A and part B claims together to meet the requisite amount in controversy for a hearing. HMO, CMP and HCPP appellants under part 417 of this chapter may combine part A and part B claims together to meet the requisite amounts in controversy for a hearing.

[59 FR 12181, Mar. 16, 1994]

§ 405.745 Amount in controversy ascertained after reconsideration.

For the purpose of determining whether a party to a reconsidered determination is entitled to a hearing, the amount in controversey after the reconsideration action rather than the amount in controversy initially at issue shall be controlling.

[40 FR 1026, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.747 Dismissal of request for hearing; amount in controversy less than $100.

The ALJ shall, without holding a hearing, dismiss the request for hearing if the request for hearing plainly shows that less than $100 is in controversy. If a hearing is held and the ALJ finds that the amount in controversy is less than $100, the ALJ shall dismiss the request for hearing and will not rule on the substantive issues involved in the appeal.

[37 FR 5814, Mar. 23, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.750 Time period for reopening initial, revised, or reconsidered determinations and decisions or revised decisions of an ALJ or the Departmental Appeals Board (DAB); binding effect of determination and decisions.

(a) *Reopenings concerning applications and entitlement.* A determination, or decision, or revised determination or decision made by the SSA concerning any matter under § 405.704(a), may be reopened and revised under 20 CFR 404.988 (Conditions for reopening).

(b) *Reopenings concerning a request for payment.* An initial, revised, or reconsidered determination of CMS, or a decision or revised decision of an ALJ or of the DAB, with respect to an individual's right concerning a request for payment under Medicare Part A, which is otherwise binding under 20 CFR 404.955 or 404.981 and §§ 405.708 or 405.717 of this subpart may be reopened:

(1) Within 12 months from the date of the notice of the initial or reconsidered determination to the party to such determination;

(2) After such 12-month period, but within 4 years after the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening such determination or decision (see 20 CFR 404.988(b) and 404.989); or

(3) At any time, when:

(i) Such initial, revised, or reconsidered determination or such decision or revised decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting clerical error or error on the face of the

evidence on which such determination or decision was based; or

(ii) Such initial, revised, or reconsidered determination or such decision or revised decision was procured by fraud or similar fault of the beneficiary or some other person.

[45 FR 73933, Nov. 7, 1980, as amended at 61 FR 32348, June 24, 1996; 62 FR 25853, 25855, May 12, 1997]

§ 405.753 Appeal of a categorization of a device.

(a) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subpart H—Appeals Under the Medicare Part B Program

AUTHORITY: Secs. 1102, 1842(b)(3)(C), 1869(b), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b), and 1395hh).

SOURCE: 32 FR 18028, Dec. 16, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.801 Part B appeals—general description.

(a) The Medicare carrier makes an initial determination when a request for payment for Part B benefits is submitted. If an individual beneficiary is dissatisfied with the initial determination, he or she may request, and the carrier will perform, a review of the claim. Following the carrier's review determination, the beneficiary may obtain a carrier hearing if the amount remaining in controversy is at least $100. The beneficiary is also entitled to a carrier hearing without the benefit of a review determination when the initial request for payment is not being acted upon with reasonable promptness (as defined in § 405.802). Following the carrier hearing, the beneficiary may obtain a hearing before an ALJ if the amount remaining in controversy is at least $500. If the beneficiary is dissatisfied with the decision of the ALJ, he or she may request the Departmental Appeals Board (DAB) to review the case. Following the action of the DAB, the beneficiary may file suit in Federal district court if the amount remaining in controversy is at least $1,000.

(b) The rights of a beneficiary under paragraph (a) of this section to appeal the carrier's initial determination are granted also to—

(1) A physician or supplier that furnishes services to a beneficiary and that accepts an assignment from the beneficiary, or

(2) A physician who meets the conditions of section 1842(l)(1)(A) of the Act pertaining to refund requirements for nonparticipating physicians who have not taken assignment on the claim(s) at issue.

(c) Procedures governing the determinations by SSA as to whether an individual has met basic Part B entitlement requirements are covered in subpart G of this part and 20 CFR part 404, subpart J. Subparts J and R of 20 CFR part 404 are also applicable to ALJ, DAB, and judicial review conducted under subpart H, except to the extent that specific provisions are contained in this subpart.

[62 FR 25853, May 12, 1997]

§ 405.802 Definitions.

As used in subpart H of this part, the term—

After receipt of the notice means 5 days after the date on the notice, unless it is shown that the notice was received earlier or later.

Appellant designates the beneficiary, assignee or other person or entity that has filed an appeal concerning a particular determination of benefits under Medicare part B. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Assignee means a physician or supplier who furnishes services to a beneficiary under Medicare part B and who has accepted a valid assignment executed by the beneficiary.

Assignment means the transfer by the assignor of his or her claim for payment to the assignee in return for the latter's promise not to charge more for his or her services than the carrier finds to be the reasonable charge or other approved amount.

Assignor means a beneficiary under Medicare part B whose physician or supplier has taken assignment of a claim.

Carrier means an organization which has entered into a contract with the Secretary pursuant to section 1842 of the Act and which is authorized to make determinations with respect to part B of title XVIII of the Act. For purposes of this subpart, the term carrier also refers to an intermediary that has entered into a contract with the Secretary under section 1816 of the Act and is authorized to make determinations with respect to part B provider services, as specified in § 421.5(c) of this chapter.

Common issues of law and fact, with respect to the aggregation of claims by two or more appellants to meet the minimum amount in controversy needed for an ALJ hearing, occurs when the claims sought to be aggregated are denied or reduced for similar reasons and arise from a similar fact pattern material to the reason the claims are denied.

Delivery of similar or related services, with respect to the aggregation of claims by two or more physician/supplier appellants to meet the minimum amount in controversy needed for an ALJ hearing, means like or coordinated services or items provided to the same beneficiary by the appellants.

Representative means an individual meeting the conditions described in §§ 405.870 through 405.871.

With reasonable promptness means within a period of 60 consecutive days after the receipt by the carrier of a request for payment.

[59 FR 12182, Mar. 16, 1994, as amended at 62 FR 25853, May 12, 1997]

§ 405.803 Initial determination.

(a) Carriers make initial determinations regarding claims for benefits under Medicare Part B.

(b) An initial determination for purposes of this subpart includes determinations such as the following:

(1) Whether services furnished are covered.

(2) Whether the deductible has been met.

(3) Whether the receipted bill or other evidence of payment is acceptable.

(4) Whether the charges for services furnished are reasonable.

(5) If the services furnished to a beneficiary by a physician or a supplier pursuant to an assignment under § 424.55 of this chapter are not covered because they are determined to be not reasonable and necessary under § 411.15(k) of this chapter, whether the beneficiary, physician or supplier, or a physician who meets the requirements of § 411.408, knew or could reasonably have been expected to know at the time the services were furnished that the services were not covered.

(c) The following are not initial determinations for purposes of this subpart:

(1) Any issue or factor for which SSA or CMS has sole responsibility, for example, whether an independent laboratory meets the conditions for coverage of services; whether a Medicare overpayment claim should be compromised, or collection action terminated or suspended.

(2) Any issue or factor which relates to hospital insurance benefits under Medicare Part A.

[62 FR 25853, May 12, 1997]

§ 405.804 Notice of initial determination.

After a carrier has made an initial determination on a request for payment written notice of this determination shall be mailed to each party to the determination at his last known address. The notice of the determination shall inform each party to the determination of his right to have such determination reviewed.

§ 405.805 Parties to the initial determination.

The parties to the initial determination (see § 405.803) may be any party described in § 405.802.

[64 FR 52670, Sept. 30, 1999]

§ 405.806 Effect of Initial Determination.

The initial determination is binding upon all parties to the claim for benefits unless the determination is—

(a) Reviewed in accordance with §§ 405.810 through 405.812; or

(b) Revised as a result of a reopening in accordance with § 405.841.

[62 FR 25853, May 12, 1997]

§ 405.807 Request for review of initial determination.

(a) *General.* A party to an initial determination by a carrier, that is dissatisfied with the initial determination and wants to appeal the matter, may request that the carrier review the determination. The request for review by the party to an initial determination must clearly indicate that he or she is dissatisfied with the initial determination and wants to appeal the matter. The request for review does not constitute a waiver of the party's right to a hearing (under § 405.815) after the review.

(b) *Place and method of filing a request.* A request by a party for a carrier to review the initial determination may be made in one of the following ways:

(1) In writing and filed at an office of the carrier, SSA, or CMS.

(2) By telephone to the telephone number designated by the carrier as the appropriate number for the receipt of requests for review.

(c) *Time of filing request.* (1) The carrier must provide a period of 6 months after the date of the notice of the initial determination within which the party to the initial determination may request a review.

(2) The carrier may, upon request by the party, extend the period for requesting the review of the initial determination.

[64 FR 52670, Sept. 30, 1999]

§ 405.808 Parties to the review.

The parties to the review (as provided for in § 405.807(a)) shall be the persons who were parties to the carrier's initial determination as described in § 405.805, and any other party whose rights with respect to the particular claim being reviewed may be affected by such review.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.809 Opportunity to submit evidence.

The parties to the review (as provided for in § 405.807(a)) shall have a reasonable opportunity to submit written evidence and contentions as to fact or law relative to the claim at issue.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.810 Review determination.

Subject to the provisions of §§ 405.807 through 405.809, the carrier shall review the claim in dispute and, upon the basis of the evidence of record, shall make a separate determination affirming or revising in whole or in part the findings and determination in question.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.811 Notice of review determination.

Written notice of the review determination is mailed to a party at his or her last known address. The review determination states the basis of the determination and advises the party of his or her right to a carrier hearing when the amount in controversy is $100 or more as determined in accordance with § 405.817. The notice states the place and manner of requesting a carrier hearing as well as the time limit under which a hearing must be requested (see § 405.821).

[59 FR 12182, Mar. 16, 1994]

§ 405.812 Effect of review determination.

The review determination is binding upon all parties to the review unless a carrier hearing decision is issued pursuant to a request for hearing made in accordance with § 405.821 or is revised

as a result of reopening in accordance with § 405.841.

[59 FR 12182, Mar. 16, 1994, as amended at 62 FR 25855, May 12, 1997]

§ 405.815 Amount in controversy for carrier hearing, ALJ hearing and judicial review.

Any party designated in § 405.822 is entitled to a carrier hearing after a review determination has been made by the carrier if the amount remaining in controversy is $100 or more and the party meets the requirements of § 405.821 of this subpart. To be entitled to a hearing before an ALJ following the carrier hearing, the amount remaining in controversy must be $500 or more, and for judicial review following the ALJ hearing and Departmental Appeals Board Review, the amount remaining in controversy must be $1000 or more.

[59 FR 12182, Mar. 16, 1994, as amended at 61 FR 32348, June 24, 1996]

§ 405.817 Principles for determining amount in controversy.

(a) *Individual appellants.* For the purpose of determining whether an individual appellant meets the minimum amount in controversy needed for a carrier hearing ($100) or ALJ hearing ($500), the following rules apply:

(1) The amount in controversy is computed as the actual amount charged the individual for the items and services in question, less any amount for which payment has been made by the carrier and less any deductible and coinsurance amounts applicable in the particular case.

(2) A single beneficiary may aggregate claims from two or more physicians/suppliers to meet the $100 or $500 thresholds. A single physician/supplier may aggregate claims from two or more beneficiaries to meet the $100 or $500 threshold levels of appeal.

(3) In either of the circumstances specified in paragraph (a)(2) of this section, two or more claims may be aggregated by an individual appellant to meet the amount in controversy for a carrier hearing only if the claims have previously been reviewed and a request for hearing has been made within six months after the date of the review determination(s).

(4) In either of the circumstances specified in paragraph (a)(2) of this section, two or more claims may be aggregated by an individual appellant to meet the amount in controversy for an ALJ hearing only if the claims have previously been decided by a carrier hearing officer and a request for an ALJ hearing has been made within 60 days after receipt of the carrier hearing officer decision(s).

(5) When requesting a carrier hearing or an ALJ hearing, the appellant must specify in his or her appeal request the specific claims to be aggregated.

(b) *Two or more appellants.* As specified in this paragraph, under section 1869(b)(2) of the Act, two or more appellants may aggregate their claims together to meet the minimum amount in controversy needed for an ALJ hearing ($500). The right to aggregate under this statutory provision applies to claims for items and services furnished on or after January 1, 1987.

(1) The aggregate amount in controversy is computed as the actual amount charged the individual(s) for the items and services in question, less any amount for which payment has been made by the carrier and less any deductible and coinsurance amounts applicable in the particular case.

(2) In determining the amount in controversy, two or more appellants may aggregate their claims together under the following circumstances:

(i) Two or more beneficiaries may combine claims representing services from the same or different physician(s) or supplier(s) if the claims involve common issues of law and fact;

(ii) Two or more physicians/suppliers may combine their claims if the claims involve the delivery of similar or related services to the same beneficiary;

(iii) Two or more physicians/suppliers may combine their claims if the claims involve common issues of law and fact with respect to services furnished to two or more beneficiaries.

(iv) In any of the circumstances specified in paragraphs (b)(2)(i) through (b)(2)(iii) of this section, the claims may be aggregated only if the claims have previously been decided by a carrier hearing officer(s) and a request for ALJ hearing has been made within 60

days after receipt of the carrier hearing officer decision(s). Moreover, in a request for ALJ hearing, the appellants must specify the claims that they seek to aggregate.

(c) The determination as to whether the amount in controversy is $100 or more is made by the carrier hearing officer. The determination as to whether the amount in controversy is $500 or more is made by the ALJ.

(d) In determining the amount in controversy under paragraph (b) of this section, the ALJ will also make the determination as to what constitutes ''similar or related services'' or ''common issues of law and fact.''

(e) When a civil action is filed by either an individual appellant or two or more appellants, the Secretary may assert that the aggregation principles contained in this subpart may be applied to determine the amount in controversy for judicial review ($1000).

(f) Notwithstanding the provisions of paragraphs (a)(1) and (b)(1) of this section, when payment is made for certain excluded services under § 411.400 of this chapter or the liability of the beneficiary for those services is limited under § 411.402 of this chapter, the amount in controversy is computed as the amount that would have been charged the beneficiary for the items or services in question, less any deductible and coinsurance amounts applicable in the particular case, had such expenses not been paid under § 411.400 of this chapter or had such liability not been limited under § 411.402 of this chapter.

(g) Under this subpart, an appellant may not combine part A and part B claims together to meet the requisite amount in controversy for a carrier hearing or ALJ hearing. HMO, CMP and HCPP appellants under part 417 of this chapter may combine part A and part B claims together to meet the requisite amount in controversy for a hearing.

[59 FR 12182, Mar. 16, 1994]

§ 405.821 Request for carrier hearing.

(a) A request for a carrier hearing is any clear expression in writing by a claimant asking for a hearing to adjudicate a claim when not acted upon with reasonable promptness or by a party to a review determination who states, in effect, that he or she is dissatisfied with the carrier's review determination and wants further opportunity to appeal the matter to the carrier.

(b) The hearing request must be filed at an office of the carrier or at an office of SSA or CMS.

(c) Except when a carrier hearing is held because the carrier did not act upon a claim with reasonable promptness, a party to the review determination may request a carrier hearing within six months after the date of the notice of the review determination. The carrier may, upon request by the party affected, extend the period for filing the request for hearing.

[59 FR 12183, Mar. 16, 1994, as amended at 62 FR 25855, May 12, 1997]

§ 405.822 Parties to a carrier hearing.

The parties to a hearing shall be the persons who were parties to the carrier's review determination (§ 405.808) which is in question. Any other person may be made a party if that person's rights with respect to supplementary medical insurance benefits may be prejudiced by the decision.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994]

§ 405.823 Carrier hearing officer.

Any hearing provided for in this subpart shall be conducted by a hearing officer designated by the appropriate official of the carrier.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.824 Disqualification of carrier hearing officer.

A hearing officer shall not conduct a hearing in any case in which he is prejudiced or partial with respect to any party, or if he has any interest in the matter before him. Notice of any objection with respect to the hearing officer who will conduct the hearing shall be made by the objecting party at his earliest opportunity. The hearing officer shall consider such objection and shall, at his discretion, withdraw. If the hearing officer withdraws, the appropriate

official of the carrier shall designate another hearing officer to conduct the hearing. If the hearing officer does not withdraw, the objecting party may present his objections to the carrier for consideration at any time prior to the issuance of a decision. The carrier shall review the request and take appropriate action. The fact that a hearing officer is an employee of the carrier may not serve as prima facie cause for disqualification.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994]

§ 405.825 Location of carrier hearing.

(a) *Time and place.* The hearing officer shall fix a time and place for the hearing reasonably convenient to the requesting party and not inconsistent with the public interest.

(b) *Adjournment or postponement.* The hearing officer may, for a good and sufficient reason, fix a new time and/or place for the hearing; he may change the time and place for the hearing or adjourn the hearing on his own motion upon reasonable notification to the parties.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994]

§ 405.826 Notice of carrier hearing.

The notice of hearing is to include notice of the time and place of the hearing; information as to the specific issues to be determined; and the matters on which findings will be made and conclusions will be reached. The notice is to contain sufficient information about the hearing procedure (including the party's right to representation) for effective preparation for the hearing.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994]

§ 405.830 Conduct of the carrier hearing.

(a) *General.* Hearings shall be open to the parties and to such other persons as the hearing officer deems necessary and proper for the orderly and efficient conduct of the hearing. The hearing officer shall inquire fully into the matters at issue and shall receive in evidence the testimony of witnesses and any documents which are relevant and material to such matters. The parties shall be provided an opportunity to enter any objection to the inclusion of any document. The order in which evidence and allegations shall be presented and the procedure at the hearing, except as this subpart otherwise expressly provides, shall be at the discretion of the hearing officer and of such nature as to afford the parties a proper hearing.

(b) *Evidence.* Evidence may be received at the hearing even though inadmissible under rules of evidence applicable to court procedures.

(c) *Witnesses.* The hearing officer may examine the witnesses and shall allow the parties or their representatives to do so. If the hearing officer conducts the examination of a witness, he may allow the parties to suggest matters upon which they desire the witness to be questioned, and the hearing officer shall question the witness with respect to such matters if they are relevant and material to any issue pending for decision before him.

(d) *Oral argument and written allegations.* The parties, upon their request shall be allowed a reasonable time for the presentation of oral argument or for the filing of briefs or other written statements or allegations of facts or law.

(e) *Consolidated issues.* When one or more new issues are raised at any time after a request for hearing has been made, but before the mailing of notice of the decision, the hearing officer may, at his discretion, consider the issues along with the other issues pending before him on the same request for hearing.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994]

§ 405.831 Waiver of right to appear at carrier hearing and present evidence.

If all parties waive their right to appear before the hearing officer and present evidence and contentions personally or by representative, it shall not be necessary for the hearing officer to give notice of or conduct a formal hearing as provided in §§ 405.825

through 405.830. A waiver of the right to appear is to be in writing and filed with the hearing officer or the carrier. Such waiver may be withdrawn by a party at any time prior to the mailing of notice of the decision in the case. Even though all of the parties have filed a waiver of the right to appear and present evidence and contentions at a hearing before the hearing officer, the hearing officer may, nevertheless, give notice of a time and place and conduct a hearing as provided in §§ 405.825 through 405.830, if he believes that the personal appearance and testimony of the party or parties would assist him to ascertain the facts at issue in the case. For purposes of this section, failure of the parties to appear shall not be cause for a finding of abandonment and the hearing officer shall make his decision on the basis of all evidence adduced.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.832 Dismissal of request for carrier hearing.

(a) *By application of party*. With the approval of the hearing officer, a request for a hearing may be withdrawn or dismissed at any time prior to the mailing of notice of the decision upon the application of the party or parties filing the request for such hearing. A party may request a dismissal by filing a written notice of such request with the carrier, the hearing officer or orally stating such request at the hearing. The dismissal of a request for hearing shall be binding unless vacated (see paragraph (d) of this section).

(b) *Dismissal by abandonment of party*. A hearing officer may dismiss a request for hearing upon abandonment by the party or parties who filed the request. A party shall be deemed to have abandoned a request for hearing, other than where personal appearance is waived in accordance with § 405.831, if neither the party nor his representative appears at the time and place fixed for the hearing and within 10 days after the mailing of a notice to him by the hearing officer to show cause, such party does not show good and sufficient cause for such failure to appear and failure to notify the hearing officer prior to the time fixed for hearing that he cannot appear.

(c) *Dismissal for cause*. The hearing officer may, on his own motion, dismiss a hearing request, either entirely or as to any stated issue, under either of the following circumstances:

(1) Where the party requesting a hearing is not a proper party under § 405.822 or does not otherwise have a right to a hearing under section 1842(b)(3)(C) of the Act; or

(2) Where the party who filed the hearing request dies and there is no information before the hearing officer showing that an individual who is not a party may be prejudiced by the carrier's determination.

(d) *Dismissal without prejudice*. The hearing officer may on his own motion dismiss without prejudice a hearing request where the amount in controversy is less than $100.

(e) *Vacation of dismissal*. A hearing officer may, on request of a party and for good and sufficient cause shown, vacate any dismissal of a request for hearing at any time within 6 months from the date of mailing notice of the dismissal to the party requesting the hearing at his last known address.

[32 FR 18028, Dec. 16, 1967, as amended at 39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994; 62 FR 25855, May 12, 1997]

§ 405.833 Record of carrier hearing.

A complete record of the proceedings at the carrier hearing is made. The testimony is transcribed and copies of other documentary evidence are reproduced in any case when directed by the hearing officer, the carrier, or CMS. The record will also be transcribed and reproduced at the request of any party to the hearing provided the requesting party bears the cost.

[62 FR 25853, May 12, 1997]

§ 405.834 Carrier hearing officer's decision.

(a) As soon as practicable after the close of a carrier hearing, the carrier hearing officer issues a decision in the case based upon the evidence presented at the hearing or otherwise included in the hearing record. The decision is issued as a written notice to the parties and contains—

(1) Findings of fact,

(2) A statement of reasons, and

(3) Notification to the parties of their right to an ALJ hearing when the amount remaining in controversy is at least $500.

(b) A copy of the decision is mailed to the parties to the hearing at their last known addresses.

[62 FR 25854, May 12, 1997]

§ 405.835 Effect of carrier hearing officer's decision.

The carrier hearing officer's decision is binding upon all parties to the hearing unless—

(a) A request for an ALJ hearing is filed in accordance with § 405.855, or

(b) The decision is revised in accordance with § 405.841.

[62 FR 25854, May 12, 1997]

§ 405.836 Authority of the carrier hearing officer.

The carrier hearing officer, in adjudicating Medicare Part B claims, complies with all of the provisions of, and regulations issued under, title XVIII of the Act, as well as with CMS Rulings, national coverage decisions, and other policy statements, instructions, and guides issued by CMS.

[62 FR 25854, May 12, 1997]

§ 405.841 Reopening initial or review determination of the carrier, and decision of a carrier hearing officer.

An initial or review determination of a carrier or a decision of a hearing officer may be reopened by such carrier or hearing officer:

(a) Within 12 months from the date of the notice of such initial or review determination or decision to the party to such determination or decision; or

(b) After such 12-month period, but within 4 years from the date of the notice of the initial determination to the party to such determination, upon establishment of good cause for reopening such determination or decision (see 20 CFR 404.988(b) and 404.989); or

(c) At any time, when:

(1) Such initial or review determination or decision was procured by fraud or similar fault of the beneficiary or some other person, or

(2) Such initial or review determination or decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error or error on the face of the evidence on which such determination or decision was based.

[39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 12183, Mar. 16, 1994; 62 FR 25855, May 12, 1997]

§ 405.842 Notice of reopening and revision.

(a) *Notice*. When any determination or decision is reopened as provided in § 405.841, notice of such reopening shall be mailed to the parties to such determination or decision at their last known addresses. A notice of revision following a reopening of a decision, shall be mailed to the parties and shall state the basis for the revised determination or decision.

(b) *Effect of revised determination*. The revision of a determination (see § 405.841) shall be binding upon all parties thereto unless a party files a written request for a hearing with respect to a revised determination when the amount in controversy is $100 or more.

[32 FR 18028, Dec. 16, 1967, as amended at 39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977; 62 FR 25855, May 12, 1997]

§ 405.850 Change of ruling or legal precedent.

Change of a legal interpretation or administrative ruling upon which a determination or decision was made shall not be considered as good and sufficient reason for reopening the determination or decision.

§ 405.853 Expedited appeals process.

(a) *Conditions for use of expedited appeals process (EAP)*. A party may use the EAP set forth in § 405.718 of this chapter to request court review in place of the ALJ hearing or Departmental Appeals Board (DAB) review if the following conditions are met:

(1) The carrier hearing officer has made a decision; an ALJ has made a hearing decision; or DAB review has been requested, but a final decision has not been issued.

(2) The filing entity is a party referred to in § 405.718(d) of this chapter.

(3) The party has filed a request for an ALJ hearing in accordance with § 405.855, or DAB review in accordance with 20 CFR 404.968.

(4) The amount remaining in controversy is $1,000 or more.

(5) If there is more than one party to the hearing decision, each party concurs, in writing, with the request for an EAP.

(b) *Content of the request for EAP*. The request for an EAP:

(1) Alleges that there are no material issues of fact in dispute; and

(2) Asserts that the only factor precluding a decision favorable to the party is a statutory provision that is unconstitutional or a regulation, national coverage decision under section 1862(a)(1) of the Act, or CMS Ruling that is invalid.

[62 FR 25854, May 12, 1997]

§ 405.855 ALJ hearing.

(a) *Right to hearing*. A party to the carrier hearing has a right to a hearing before an ALJ if—

(1) The party files a written request for an ALJ hearing within 60 days after receipt of the notice of the carrier hearing decision; and

(2) The amount remaining in controversy is $500 or more.

(b) *Place of filing hearing request*. The request for an ALJ hearing must be made in writing and filed with the carrier that issued the decision, a Social Security office, or, in the case of a qualified railroad retirement beneficiary, an office of the Railroad Retirement Board.

(c) *Effect of ALJ hearing decision*. (1) An ALJ's decision is binding on all parties to the hearing unless—

(i) The DAB reviews the ALJ decision;

(ii) The DAB does not review the ALJ decision, and the party requests judicial review;

(iii) The decision is revised by the DAB or an ALJ in accordance with the provisions of § 405.750 of this chapter; or

(iv) The expedited appeals process is used.

[62 FR 25854, May 12, 1997]

§ 405.856 Departmental Appeals Board (DAB) review.

Regulations beginning at 20 CFR 404.967 regarding SSA Appeals Council Review are applicable to DAB review of matters addressed by this subpart.

[62 FR 25854, May 12, 1997]

§ 405.857 Court review.

(a) *General rule*. To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a DAB decision, or an ALJ decision if the DAB does not review the ALJ's decision, may obtain a court review if the amount remaining in controversy is $1,000 or more. A party may obtain court review by filing a civil action in a district court of the United States in accordance with the provisions of section 205(g) of the Act. The filing procedure is set forth in 20 CFR 422.210.

(b) *Prohibition against court review of certain Part B regulations or instructions*. Under section 1869(b)(4) of the Act, a court may not review a regulation or instruction that relates to a method of payment under Part B if the regulation was promulgated, or the instruction issued, before January 1, 1981.

[62 FR 25854, May 12, 1997]

§ 405.860 Review of a national coverage determination (NCD).

(a) *General rule*. (1) An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under title XVIII of the Act.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under title XVIII or a determination for the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act.

(4) An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs.

(b) *Review by ALJ*. (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for

benefits and, if so, whether the NCD is applied correctly to the claim.

(c) *Review by Court.* For initial determinations and NCD challenges under section 1862(a)(1) of the Act, arising before October 1, 2002, a court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case is remanded to the Secretary to supplement the record regarding the NCD. In these cases, the court may not invalidate an NCD except upon review of the supplemental record.

[68 FR 63716, Nov. 7, 2003]

§ 405.870 Appointment of representative.

A party to an initial determination, informal review or hearing as provided in §§ 405.803 through 405.934, may appoint as his representative in any such proceeding any person qualified under § 405.871. Where the representative is an attorney, in the absence of information to the contrary, his representation that he has such authority shall be accepted as evidence of the attorney's authority to represent a party.

§ 405.871 Qualifications of representatives.

Any individual may be appointed to act as representative in accordance with § 405.870, unless he is disqualified or suspended from acting as a representative in proceedings before the SSA or the CMS or unless otherwise prohibited by law.

[39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 62 FR 25855, May 12, 1997]

§ 405.872 Authority of representatives.

A representative, appointed and qualified as provided in §§ 405.870 and 405.871, may make or give, on behalf of the party he represents, any request or notice relative to any proceeding before the carrier including review and hearing. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to the claim of such party to the same extent as such party. Notice to any party or any action, determination, or decision, or request to any party for the production of evidence, shall be sent to the representative of such party.

§ 405.874 Appeals of carrier decisions that supplier standards are not met.

(a) An entity serving as a National Supplier Clearinghouse must act promptly to determine if any entity submitting a request for a billing number as a Medicare supplier of part B items meets the standards set forth in part 424. Effective July 1, 1993, the National Supplier Clearinghouse must accept, reject or request additional information within 15 days of the receipt of an enrollment application.

(b) If the National Supplier Clearinghouse disallows an entity's request for a billing number or revokes, with the concurrence of CMS, an entity's billing number, the National Supplier Clearinghouse notifies the entity by certified mail. Revocation is effective 15 days after the National Supplier Clearinghouse mails notice of its determination. The carrier disallows payment for items furnished by the supplier beginning with that effective date. The notice must inform the entity of the reason for the rejection or revocation, its right to appeal, the date by which it must file that appeal (90 days after the postmark of the notice) and the address to which the appeal must be sent in writing.

(c) A fair hearing officer not involved in the original determination to disallow an entity's request for a billing number, or to revoke an entity's billing number, must schedule a hearing to be held within one week of receipt of an appeal, or later at the request of the entity. Both the entity and carrier may offer evidence. The hearing officer issues notice of his/her decision within 2 weeks of the hearing. The notice is sent by certified letter to CMS, the carrier, and the appealing entity. This notice must include information about the supplier's further right to appeal, the carrier's right to appeal, the date by which the appeal must be filed (90 days after the postmark of the notice) and the address to which the appeals

must be sent in writing. Either the carrier or entity may appeal the hearings officer's decision to CMS.

(d) A CMS official, designated by the Administrator of CMS, must make an appeal decision based on the evidence presented to the fair hearing officer and his or her decision. The CMS official requests any additional information he or she deems necessary from either the carrier or the entity within two weeks of receipt by the CMS of the appeal. Notice of the CMS official's decision—

(1) Is issued within two weeks of when the last information is received is received by the CMS official, or four weeks of when the information is requested, whichever is shorter, unless the party appealing the fair hearing decision requests a delay;

(2) Is sent by the CMS official by certified mail to both the carrier and the entity; and

(3) Contains information on any further appeals the entity and carrier may have.

(e) A billing number is not issued, or remains revoked, and payment is not made, for items or services furnished by any entity which a carrier determines does not qualify for a billing number, until the carrier (upon reapplication of the entity), a fair hearing officer, or a CMS official designated to hear such appeals, determines that the entity qualifies for a billing number. Any claims for items or services furnished after revocation of the supplier's billing number and submitted by the entity during the appeals period are held and not processed, i.e., are neither approved, denied or developed, until all administrative appeals have been exhausted. If an entity is determined not to have qualified for a billing number in one period but to have qualified in another, the carrier pays for claims for items sold or rented to beneficiaries during the period the entity qualified as a supplier. If there is evidence of an overpayment, see subpart C of part 405 of this Chapter.

(f) A billing number may be reinstated after revocation when an entity completes a corrective action plan, to which CMS has agreed, and provided sufficient assurance of its intent to comply fully with the supplier standards.

[57 FR 27305, June 18, 1992]

§ 405.877 Appeal of a categorization of a device.

(a) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, CMS's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subpart I—Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B)

SOURCE: 70 FR 11472, Mar. 8, 2005, unless otherwise noted.

§ 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the provisions of sections 1869 (a) through (e) and (g) of the Act.

(b) *Scope.* This subpart establishes the requirements for appeals of initial determinations for benefits under Part A or Part B of Medicare, including the following:

(1) The initial determination of whether an individual is entitled to benefits under Part A or Part B. (Regulations governing reconsiderations of these initial determinations are at 20 CFR, part 404, subpart J).

(2) The initial determination of the amount of benefits available to an individual under Part A or Part B.

(3) Any other initial determination relating to a claim for benefits under

Part A or Part B, including an initial determination made by a quality improvement organization under section 1154(a)(2) of the Act or by an entity under contract with the Secretary (other than a contract under section 1852 of the Act) to administer provisions of titles XVIII or XI of the Act.

§ 405.902 Definitions.

For the purposes of this subpart, the term—

ALJ means an Administrative Law Judge of the Department of Health and Human Services.

Appellant means the beneficiary, assignee or other person or entity that has filed and pursued an appeal concerning a particular initial determination. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Appointed representative means an individual appointed by a party to represent the party in a Medicare claim or claim appeal.

Assignee means:

(1) A supplier that furnishes items or services to a beneficiary and has accepted a valid assignment of a claim or

(2) A provider or supplier that furnishes items or services to a beneficiary, who is not already a party, and has accepted a valid assignment of the right to appeal a claim executed by the beneficiary.

Assignment of a claim means the transfer by a beneficiary of his or her claim for payment to the supplier in return for the latter's promise not to charge more for his or her services than what the carrier finds to be the Medicare-approved amount, as provided in § 424.55 and § 424.56 of this chapter.

Assignment of appeal rights means the transfer by a beneficiary of his or her right to appeal under this subpart to a provider or supplier who is not already a party, as provided in section 1869(b)(1)(C) of the Act.

Assignor means a beneficiary whose provider of services or supplier has taken assignment of a claim or an appeal of a claim.

Authorized representative means an individual authorized under State or other applicable law to act on behalf of a beneficiary or other party involved in the appeal. The authorized representative will have all of the rights and responsibilities of a beneficiary or party, as applicable, throughout the appeals process.

Beneficiary means an individual who is enrolled to receive benefits under Medicare Part A or Part B.

Carrier means an organization that has entered into a contract with the Secretary in accordance to section 1842 of the Act and is authorized to make determinations for Part B of title XVIII of the Act.

Clean claim means a claim that has no defect or impropriety (including any lack of required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under title XVIII within the time periods specified in sections 1816(c) and 1842(c) of the Act.

Family member means for purposes of the QIC reconsideration panel under § 405.968 the following persons as they relate to the physician or healthcare provider.

(1) The spouse (other than a spouse who is legally separated from the physician or health care professional under a decree of divorce or separate maintenance);

(2) Children (including stepchildren and legally adopted children);

(3) Grandchildren;

(4) Parents; and

(5) Grandparents.

Fiscal Intermediary means an organization that has entered into a contract with CMS in accordance with section 1816 of the Act and is authorized to make determinations and payments for Part A of title XVIII of the Act, and Part B provider services as specified in § 421.5(c) of this chapter.

MAC stands for the Medicare Appeals Council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

Party means an individual or entity listed in § 405.906 that has standing to appeal an initial determination and/or a subsequent administrative appeal determination.

Provider means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or

hospice that has in effect an agreement to participate in Medicare, or clinic, rehabilitation agency, or public health agency that has in effect a similar agreement, but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Qualified Independent Contractor (QIC) means an entity which contracts with the Secretary in accordance with section 1869 of the Act to perform reconsiderations under § 405.960 through § 405.978.

Quality Improvement Organization (QIO) means an entity that contracts with the Secretary in accordance with sections 1152 and 1153 of the Act and 42 CFR subchapter F, to perform the functions described in section 1154 of the Act and 42 CFR subchapter F, including expedited determinations as described in § 405.1200 through § 405.1208.

Reliable evidence means evidence that is relevant, credible, and material.

Remand means to vacate a lower level appeal decision, or a portion of the decision, and return the case, or a portion of the case, to that level for a new decision.

Similar fault means to obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that he or she filed a proper claim as defined in part 411 of this chapter.

Supplier means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under Medicare.

Vacate means to set aside a previous action.

§ 405.904 Medicare initial determinations, redeterminations and appeals: General description.

(a) *General overview.* (1) *Entitlement appeals.* The SSA makes an initial determination on an application for Medicare benefits and/or entitlement of an individual to receive Medicare benefits. A beneficiary who is dissatisfied with the initial determination may request, and SSA will perform, a reconsideration in accordance with 20 CFR part 404, subpart J if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an Administrative Law Judge (ALJ) under this subpart (42 CFR part 405, subpart I). If the beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, he or she may request the Medicare Appeals Council (MAC) to review the case. Following the action of the MAC, the beneficiary may be entitled to file suit in Federal district court.

(2) *Claim appeals.* The Medicare contractor makes an initial determination when a claim for Medicare benefits under Part A or Part B is submitted. A beneficiary who is dissatisfied with the initial determination may request that the contractor perform a redetermination of the claim if the requirements for obtaining a redetermination are met. Following the contractor's redetermination, the beneficiary may request, and the Qualified Independent Contractor (QIC) will perform, a reconsideration of the claim if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request, and the ALJ will conduct a hearing if the amount remaining in controversy and other requirements for an ALJ hearing are met. If the beneficiary is dissatisfied with the decision of the ALJ, he or she may request the MAC to review the case. If the MAC reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met.

(b) *Non-beneficiary appellants.* In general, the procedures described in paragraph (a) of this section are also available to parties other than beneficiaries either directly or through a representative acting on a party's behalf, consistent with the requirements of this subpart I. A provider generally has the

right to judicial review only as provided under section 1879(d) of the Act; that is, when a determination involves a finding that services are not covered because—

(1) They were custodial care (see § 411.15(g) of this chapter); they were not reasonable and necessary (see § 411.15(k) of this chapter); they did not qualify as covered home health services because the beneficiary was not confined to the home or did not need skilled nursing care on an intermittent basis (see § 409.42(a) and (c)(1) of this chapter); or they were hospice services provided to a non-terminally ill individual (see § 418.22 of this chapter); and

(2) Either the provider or the beneficiary, or both, knew or could reasonably be expected to know that those services were not covered under Medicare.

§ 405.906 Parties to the initial determinations, redeterminations, reconsiderations, hearings and reviews.

(a) *Parties to the initial determination.* The parties to the initial determination are the following individuals and entities:

(1) A beneficiary who files a claim for payment under Medicare Part A or Part B or has had a claim for payment filed on his or her behalf, or in the case of a deceased beneficiary, when there is no estate, any person obligated to make or entitled to receive payment in accordance with part 424, subpart E of this chapter. Payment by a third party payer does not entitle that entity to party status.

(2) A supplier who has accepted assignment for items or services furnished to a beneficiary that are at issue in the claim.

(3) A provider of services who files a claim for items or services furnished to a beneficiary.

(b) *Parties to the redetermination, reconsideration, hearing and MAC.* The parties to the redetermination, reconsideration, hearing, and MAC review are—

(1) The parties to the initial determination in accordance with paragraph (a) of this section, except under paragraph (a)(1) of this section where a beneficiary has assigned appeal rights under § 405.912;

(2) A State agency in accordance with § 405.908;

(3) A provider or supplier that has accepted an assignment of appeal rights from the beneficiary according to § 405.912;

(4) A non-participating physician not billing on an assigned basis who, in accordance with section 1842(l) of the Act, may be liable to refund monies collected for services furnished to the beneficiary because those services were denied on the basis of section 1862(a)(1) of the Act; and

(5) A non-participating supplier not billing on an assigned basis who, in accordance with sections 1834(a)(18) and 1834(j)(4) of the Act, may be liable to refund monies collected for items furnished to the beneficiary.

(c) *Appeals by providers and suppliers when there is no other party available.* If a provider or supplier is not already a party to the proceeding in accordance with paragraphs (a) and (b) of this section, a provider of services or supplier may appeal an initial determination relating to services it rendered to a beneficiary who subsequently dies if there is no other party available to appeal the determination.

§ 405.908 Medicaid State agencies.

When a beneficiary is enrolled to receive benefits under both Medicare and Medicaid, the Medicaid State agency may file a request for an appeal with respect to a claim for items or services furnished to a dually eligible beneficiary only for services for which the Medicaid State agency has made payment, or for which it may be liable. A Medicaid State agency is considered a party only when it files a timely redetermination request with respect to a claim for items or services furnished to a beneficiary in accordance with 42 CFR parts 940 through 958. If a State agency files a request for redetermination, it may retain party status at the QIC, ALJ, MAC, and judicial review levels.

§ 405.910 Appointed representatives.

(a) *Scope of representation.* An appointed representative may act on behalf of an individual or entity in exercising his or her right to an initial determination or appeal. Appointed representatives do not have party status and may take action only on behalf of the individual or entity that they represent.

(b) *Persons not qualified.* A party may not name as an appointed representative, an individual who is disqualified, suspended, or otherwise prohibited by law from acting as a representative in any proceedings before DHHS, or in entitlement appeals, before SSA.

(c) *Completing a valid appointment.* For purposes of this subpart, an appointment of representation must:

(1) Be in writing and signed and dated by both the party and individual agreeing to be the representative;

(2) Provide a statement appointing the representative to act on behalf of the party, and in the case of a beneficiary, authorizing the adjudicator to release identifiable health information to the appointed representative.

(3) Include a written explanation of the purpose and scope of the representation;

(4) Contain both the party's and appointed representative's name, phone number, and address;

(5) Identify the beneficiary's Medicare health insurance claim number;

(6) Include the appointed representative's professional status or relationship to the party;

(7) Be filed with the entity processing the party's initial determination or appeal.

(d) *Curing a defective appointment of representative.*

(1) If any one of the seven elements named in paragraph (c) of this section is missing from the appointment, the adjudicator should contact the party and provide a description of the missing documentation or information.

(2) Unless the defect is cured, the prospective appointed representative lacks the authority to act on behalf of the party, and is not entitled to obtain or receive any information related to the appeal, including the appeal decision.

(e) *Duration of appointment.* (1) Unless revoked, an appointment is considered valid for 1 year from the date that the Appointment of Representative (AOR) form or other conforming written instrument contains the signatures of both the party and the appointed representative.

(2) To initiate an appeal within the 1-year time frame, the representative must file a copy of the AOR form, or other conforming written instrument, with the appeal request. Unless revoked, the representation is valid for the duration of an individual's appeal of an initial determination.

(3) For an initial determination of a Medicare Secondary Payer recovery claim, an appointment signed in connection with the party's efforts to make a claim for third party payment is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked.

(f) *Appointed representative fees.* (1) *General rule.* An appointed representative for a beneficiary who wishes to charge a fee for services rendered in connection with an appeal before the Secretary must obtain approval of the fee from the Secretary. Services rendered below the ALJ level are not considered proceedings before the Secretary.

(2) *No fees or costs against trust funds.* No award of attorney or any other representative's fees or any costs in connection with an appeal may be made against the Medicare trust funds.

(3) *Special rules for providers and suppliers.* A provider or supplier that furnished the items or services to a beneficiary that are the subject of the appeal may represent that beneficiary in an appeal under this subpart, but the provider or supplier may not charge the beneficiary any fee associated with the representation. If a provider or supplier furnishes services or items to a beneficiary, the provider or supplier may not represent the beneficiary on the issues described in section 1879(a)(2) of the Act, unless the provider or supplier waives the right to payment from the beneficiary for the services or items involved in the appeal.

(4) *Special rules for purposes of third party payment.* The Secretary does not review fee arrangements made by a beneficiary for purposes of making a

claim for third party payment (as defined in 42 CFR 411.21) even though the representation may ultimately include representation for a Medicare Secondary Payer recovery claim.

(5) *Reasonableness of representative fees.* In determining the reasonableness of a representative's fee, the Secretary will not apply the test specified in sections 206(a)(2) and (a)(3) of the Act.

(g) *Responsibilities of an appointed representative.* (1) An appointed representative has an affirmative duty to—

(i) Inform the party of the scope and responsibilities of the representation;

(ii) Inform the party of the status of the appeal and the results of actions taken on behalf of the party, including, but not limited to, notification of appeal determinations, decisions, and further appeal rights;

(iii) Disclose to a beneficiary any financial risk and liability of a non-assigned claim that the beneficiary may have;

(iv) Not act contrary to the interest of the party; and

(v) Comply with all laws and CMS regulations, CMS Rulings, and instructions.

(2) An appeal request filed by a provider or supplier described in paragraph (f)(3) of this section must also include a statement signed by the provider or supplier stating that no financial liability is imposed on the beneficiary in connection with that representation. If applicable, the appeal request must also include a signed statement that the provider or supplier waives the right to payment from the beneficiary for services or items regarding issues described in section 1879(a)(2) of the Act.

(h) *Authority of an appointed representative.* An appointed representative may, on behalf of the party—

(1) Obtain appeals information about the claim to the same extent as the party;

(2) Submit evidence;

(3) Make statements about facts and law; and

(4) Make any request, or give, or receive, any notice about the appeal proceedings.

(i) *Notice or request to an appointed representative.*

(1) *Initial determinations.* When a contractor takes an action or issues an initial determination, it sends the action or notice to the party.

(2) *Appeals.* When a contractor, QIC, ALJ, or the MAC takes an action or issues a redetermination, reconsideration, or appeal decision, in connection with an initial determination, it sends notice of the action to the appointed representative.

(3) The contractor, QIC, ALJ or MAC sends any requests for information or evidence regarding a claim that is appealed to the appointed representative. The contractor sends any requests for information or evidence regarding an initial determination to the party.

(4) For initial determinations and appeals involving Medicare Secondary Payer recovery claims, the adjudicator sends notices and requests to both the beneficiary and the appointed representative.

(j) *Effect of notice or request to an appointed representative.* A notice or request sent to the appointed representative has the same force and effect as if was sent to the party.

(k) *Information available to the appointed representative.* An appointed representative may obtain any and all appeals information applicable to the claim at issue that is available to the party.

(l) *Delegation of appointment by appointed representative.* An appointed representative may not designate another individual to act as the appointed representative of the party unless—

(1) The appointed representative provides written notice to the party of the appointed representative's intent to delegate to another individual. The notice must include:

(i) The name of the designee; and

(ii) The designee's acceptance to be obligated and comply with the requirements of representation under this subpart.

(2) The party accepts the designation as evidenced by a written statement signed by the party. This signed statement is not required when the appointed representative and designee are attorneys in the same law firm or organization.

(m) *Revoking the appointment of representative.* (1) A party may revoke an appointment of representative without cause at any time.

(2) *Revocation.* Revocation is not effective until the adjudicator receives a signed, written statement from the party.

(3) *Death of the party.* (i) The death of a party terminates the authority of the appointed representative, except as specified in paragraph (m)(3)(ii) of this section.

(ii) A party's death does not terminate an appeal that is in progress if another individual or entity may be entitled to receive or obligated to make payment for the items or services that are the subject of the appeal. The appointment of representative remains in effect for the duration of the appeal except for MSP recovery claims.

§ 405.912 Assignment of appeal rights.

(a) *Who may be an assignee.* Only a provider, or supplier that—

(1) Is not a party to the initial determination as defined in § 405.906; and

(2) Furnished an item or service to the beneficiary may seek assignment of appeal rights from the beneficiary for that item or service.

(b) *Who may not be an assignee.* An individual or entity who is not a provider or supplier may not be an assignee. A provider or supplier that furnishes an item or service to a beneficiary may not seek assignment for that item or service when considered a party to the initial determination as defined in § 405.906.

(c) *Requirements for a valid assignment of appeal right.* The assignment of appeal rights must—

(1) Be executed using a CMS standard form;

(2) Be in writing and signed by both the beneficiary assigning his or her appeal rights and by the assignee;

(3) Indicate the item or service for which the assignment of appeal rights is authorized;

(4) Contain a waiver of the assignee's right to collect payment from the assignor for the specific item or service that are the subject of the appeal except as set forth in paragraph (d)(2) of this section; and

(5) Be submitted at the same time the request for redetermination or other appeal is filed.

(d) *Waiver of right to collect payment.* (1) Except as specified in paragraph (d)(2) of this section, the assignee must waive the right to collect payment for the item or service for which the assignment of appeal rights is made. If the assignment is revoked under paragraph (g)(2) or (g)(3) of this section, the waiver of the right to collect payment nevertheless remains valid. A waiver of the right to collect payment remains in effect regardless of the outcome of the appeal decision.

(2) The assignee is not prohibited from recovering payment associated with coinsurance or deductibles or when an advance beneficiary notice is properly executed.

(e) *Duration of a valid assignment of appeal rights.* Unless revoked, the assignment of appeal rights is valid for all administrative and judicial review associated with the item or service as indicated on the standard CMS form, even in the event of the death of the assignor.

(f) *Rights of the assignee.* When a valid assignment of appeal rights is executed, the assignor transfers all appeal rights involving the particular item or service to the assignee. These include, but are not limited to—

(1) Obtaining information about the claim to the same extent as the assignor;

(2) Submitting evidence;

(3) Making statements about facts or law; and

(4) Making any request, or giving, or receiving any notice about appeal proceedings.

(g) *Revocation of assignment.* When an assignment of appeal rights is revoked, the rights to appeal revert to the assignor. An assignment of appeal rights may be revoked in any of the following ways:

(1) *In writing by the assignor.* The revocation of assignment must be delivered to the adjudicator and the assignee, and is effective on the date of receipt by the adjudicator.

(2) By abandonment if the assignee does not file an appeal of an unfavorable decision.

(3) By act or omission by the assignee that is determined by an adjudicator to be contrary to the financial interests of the assignor.

(h) *Responsibilities of the assignee.* Once the assignee files an appeal, the assignee becomes a party to the appeal. The assignee must meet all requirements for appeals that apply to any other party.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

INITIAL DETERMINATIONS

§ 405.920 Initial determinations.

After a claim is filed with the appropriate contractor in the manner and form described in subpart C of part 424 of this chapter, the contractor must—

(a) Determine if the items and services furnished are covered or otherwise reimbursable under title XVIII of the Act;

(b) Determine any amounts payable and make payment accordingly; and

(c) Notify the parties to the initial determination of the determination in accordance with § 405.921.

§ 405.921 Notice of initial determination.

(a) *Notice of initial determination sent to the beneficiary.* (1) The notice must be written in a manner calculated to be understood by the beneficiary, and sent to the last known address of the beneficiary;

(2) *Content of the notice.* The notice of initial determination must contain—

(i) The reasons for the determination, including whether a local medical review policy, a local coverage determination, or national coverage determination was applied;

(ii) The procedures for obtaining additional information concerning the contractor's determination, such as a specific provision of the policy, manual, law or regulation used in making the determination;

(iii) Information on the right to a redetermination if the beneficiary is dissatisfied with the outcome of the initial determination and instructions on how to request a redetermination; and

(iv) Any other requirements specified by CMS.

(b) *Notice of initial determination sent to providers and suppliers.*

(1) An electronic or paper remittance advice (RA) notice is the notice of initial determination sent to providers and suppliers that accept assignment. The electronic RA must comply with the format and content requirements of the standard adopted for national use by covered entities under the Health Insurance Portability and Accountability Act (HIPAA) and related CMS manual instructions. When a paper RA is mailed, it must comply with CMS manual instructions that parallel the HIPAA data content and coding requirements.

(2) The notice of initial determination must contain:

(i) The basis for any full or partial denial determination of services or items on the claim;

(ii) Information on the right to a redetermination if the provider or supplier is dissatisfied with the outcome of the initial determination;

(iii) All applicable claim adjustment reason and remark codes to explain the determination;

(iv) The source of the RA and who may be contacted if the provider or supplier requires further information;

(v) All content requirements of the standard adopted for national use by covered entities under HIPAA; and

(vi) Any other requirements specified by CMS.

§ 405.922 Time frame for processing initial determinations.

The contractor issues initial determinations on clean claims within 30 days of receipt if they are submitted by or on behalf of the beneficiary who received the items and/or services; otherwise, interest must be paid at the rate specified at 31 U.S.C. 3902(a) for the period beginning on the day after the required payment date and ending on the date payment is made.

§ 405.924 Actions that are initial determinations.

(a) *Applications and entitlement of individuals.* SSA makes initial determinations and processes reconsiderations with respect to an individual on the following:

(1) A determination with respect to entitlement to hospital insurance or supplementary medical insurance under Medicare.

(2) A disallowance of an individual's application for entitlement to hospital or supplementary medical insurance, if the individual fails to submit evidence requested by SSA to support the application. (SSA specifies in the initial determination the conditions of entitlement that the applicant failed to establish by not submitting the requested evidence).

(3) A denial of a request for withdrawal of an application for hospital or supplementary medical insurance, or a denial of a request for cancellation of a request for withdrawal.

(4) A determination as to whether an individual, previously determined as entitled to hospital or supplementary medical insurance, is no longer entitled to those benefits, including a determination based on nonpayment of premiums.

(b) *Claims made by or on behalf of beneficiaries.* The Medicare contractor makes initial determinations regarding claims for benefits under Medicare Part A and Part B. A finding that a request for payment or other submission does not meet the requirements for a Medicare claim as defined in §424.32 of this chapter, is not considered an initial determination. An initial determination for purposes of this subpart includes, but is not limited to, determinations with respect to:

(1) If the items and/or services furnished are covered under title XVIII;

(2) In the case of determinations on the basis of section 1879(b) or (c) of the Act, if the beneficiary, or supplier who accepts assignment under §424.55 of this chapter knew, or could reasonably have expected to know at the time the items or services were furnished, that the items or services were not covered;

(3) In the case of determinations on the basis of section 1842(l)(1) of the Act, if the beneficiary or physician knew, or could reasonably have expected to know at the time the services were furnished, that the services were not covered;

(4) Whether the deductible is met;

(5) The computation of the coinsurance amount;

(6) The number of days used for inpatient hospital, psychiatric hospital, or post-hospital extended care;

(7) The number of home health visits used;

(8) Periods of hospice care used;

(9) Requirements for certification and plan of treatment for physician services, durable medical equipment, therapies, inpatient hospitalization, skilled nursing care, home health, hospice, and partial hospitalization services;

(10) The beginning and ending of a spell of illness, including a determination made under the presumptions established under §409.60(c)(2) of this chapter, and as specified in §409.60(c)(4) of this chapter;

(11) The medical necessity of services, or the reasonableness or appropriateness of placement of an individual at an acute level of patient care made by the Quality Improvement Organization (QIO) on behalf of the contractor in accordance with §476.86(c)(1) of this chapter;

(12) Any other issues having a present or potential effect on the amount of benefits to be paid under Part A or Part B of Medicare, including a determination as to whether there was an underpayment of benefits paid under Part A or Part B, and if so, the amount thereof;

(13) If a waiver of adjustment or recovery under sections 1870(b) and (c) of the Act is appropriate:

(i) When an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1814(e) of the Act) was made for an individual; or

(ii) For a Medicare Secondary Payer recovery claim against a beneficiary or against a provider or supplier.

(14) If a particular claim is not payable by Medicare based upon the application of the Medicare Secondary Payer provisions of section 1862(b) of the Act.

(15) Under the Medicare Secondary Payer provisions of sections 1862(b) of the Act that Medicare has a recovery claim against a provider, supplier, or beneficiary for services or items that were already paid by the Medicare program, except when the Medicare Secondary Payer recovery claim against

the provider or supplier is based upon failure to file a proper claim as defined in part 411 of this chapter because this action is a reopening.

(c) *Determinations by QIOs.* An initial determination for purposes of this subpart also includes a determination made by a QIO that:

(1) A provider can terminate services provided to an individual when a physician certified that failure to continue the provision of those services is likely to place the individual's health at significant risk; or

(2) A provider can discharge an individual from the provider of services.

§ 405.926 Actions that are not initial determinations.

Actions that are not initial determinations and are not appealable under this subpart include, but are not limited to—

(a) Any determination for which CMS has sole responsibility, for example—

(1) If an entity meets the conditions for participation in the program;

(2) If an independent laboratory meets the conditions for coverage of services;

(b) The coinsurance amounts prescribed by regulation for outpatient services under the prospective payment system;

(c) Any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to § 405.502(g), and any issue regarding the cost report settlement process under Part A;

(d) Whether an individual's appeal meets the qualifications for expedited access to judicial review provided in § 405.990;

(e) Any determination regarding whether a Medicare overpayment claim must be compromised, or collection action terminated or suspended under the Federal Claims Collection Act of 1966, as amended;

(f) Determinations regarding the transfer or discharge of residents of skilled nursing facilities in accordance with § 483.12 of this chapter;

(g) Determinations regarding the readmission screening and annual resident review processes required by subparts C and E of part 483 of this chapter;

(h) Determinations for a waiver of Medicare Secondary Payer recovery under section 1862(b) of the Act;

(i) Determinations for a waiver of interest;

(j) Determinations for a finding regarding the general applicability of the Medicare Secondary Payer provisions (as opposed to the application of these provisions to a particular claim or claims for Medicare payment for benefits);

(k) Determinations under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery against an entity that was or is required or responsible (directly, as an insurer or self-insurer, as a third party administrator, as an employer that sponsors or contributes to a group health plan or a large group health plan, or otherwise,) to make payment for services or items that were already reimbursed by the Medicare program;

(l) A contractor's, QIC's, ALJ's, or MAC's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, hearing decision, or review decision;

(m) Determinations that CMS or its contractors may participate in or act as parties in an ALJ hearing or MAC review;

(n) Determinations that a provider or supplier failed to submit a claim timely or failed to submit a timely claim despite being requested to do so by the beneficiary or the beneficiary's subrogee;

(o) Determinations with respect to whether an entity qualifies for an exception to the electronic claims submission requirement under part 424 of this chapter;

(p) Determinations by the Secretary of sustained or high levels of payment errors in accordance with section 1893(f)(3)(A) of the Act;

(q) A contractor's prior determination related to coverage of physicians' services;

(r) Requests for anticipated payment under the home health prospective payment system under § 409.43(c)(ii)(2) of this chapter; and

(s) Claim submissions on forms or formats that are incomplete, invalid, or do not meet the requirements for a Medicare claim and returned or rejected to the provider or supplier.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

§ 405.927 Initial determinations subject to the reopenings process.

Minor errors or omissions in an initial determination must be corrected only through the contractor's reopenings process under § 405.980(a)(3).

§ 405.928 Effect of the initial determination.

(a) An initial determination described in § 405.924(a) is binding unless it is revised or reconsidered in accordance with 20 CFR 404.907, or revised as a result of a reopening in accordance with 20 CFR 404.988.

(b) An initial determination described in § 405.924(b) is binding upon all parties to the initial determination unless—

(1) A redetermination is completed in accordance with § 405.940 through § 405.958; or

(2) The initial determination is revised as a result of a reopening in accordance with § 405.980.

(c) An initial determination listed in § 405.924(b) where a party submits a timely, valid request for redetermination under § 405.942 through § 405.944 must be processed as a redetermination under § 405.948 through § 405.958 unless the initial determination involves a clerical error or other minor error or omission.

REDETERMINATIONS

§ 405.940 Right to a redetermination.

A person or entity that may be a party to a redetermination in accordance with § 405.906(b) and that is dissatisfied with an initial determination may request a redetermination by a contractor in accordance with § 405.940 through § 405.958, regardless of the amount in controversy.

§ 405.942 Time frame for filing a request for a redetermination.

(a) *Time frame for filing a request.* Except as provided in paragraph (b) of this section, any request for redetermination must be filed within 120 calendar days from the date a party receives the notice of the initial determination.

(1) For purposes of this section, the date of receipt of the initial determination will be presumed to be 5 days after the date of the notice of initial determination, unless there is evidence to the contrary.

(2) The request is considered as filed on the date it is received by the contractor.

(b) *Extending the time frame for filing a request. General rule.* If the 120-day period in which to file a request for a redetermination has expired and a party shows good cause, the contractor may extend the time frame for filing a request for redetermination.

(1) *How to request an extension.* A party may file a request for an extension of time for filing a request for a redetermination with the contractor. The party should include any evidence supporting the request for extension. The request for redetermination extension must—

(i) Be in writing;

(ii) State why the request for redetermination was not filed within the required time frame; and

(iii) Meet the requirements of § 405.944.

(2) *How the contractor determines if good cause exists.* In determining if a party has good cause for missing a deadline to request a redetermination, the contractor considers—

(i) The circumstances that kept the party from making the request on time;

(ii) If the contractor's action(s) misled the party; and

(iii) If the party had or has any physical, mental, educational, or linguistic limitations, including any lack of facility with the English language, that prevented the party from filing a timely request or from understanding or knowing about the need to file a timely request.

(3) *Examples of good cause.* Examples of circumstances when good cause may

be found to exist include, but are not limited to, the following situations:

(i) The party was prevented by serious illness from contacting the contractor in person, in writing, or through a friend, relative, or other person; or

(ii) The party had a death or serious illness in his or her immediate family; or

(iii) Important records of the party were destroyed or damaged by fire or other accidental cause; or

(iv) The contractor gave the party incorrect or incomplete information about when and how to request a redetermination; or

(v) The party did not receive notice of the determination or decision; or

(vi) The party sent the request to a Government agency in good faith within the time limit, and the request did not reach the appropriate contractor until after the time period to file a request expired.

§ 405.944 Place and method of filing a request for a redetermination.

(a) *Filing location.* The request for redetermination must be filed with the contractor indicated on the notice of initial determination.

(b) *Content of redetermination request.* The request for redetermination must be in writing and should be made on a standard CMS form. A written request that is not made on a standard CMS form is accepted if it contains the same required elements as follows:

(1) The beneficiary's name;

(2) The Medicare health insurance claim number;

(3) Specific service(s) and/or item(s) for which the redetermination is being requested and the specific date(s) of the service;

(4) The name and signature of the party or the representative of the party.

(c) *Requests for redetermination by more than one party.* If more than one party timely files a request for redetermination on the same claim before a redetermination is made on the first timely filed request, the contractor must consolidate the separate requests into one proceeding and issue one redetermination.

§ 405.946 Evidence to be submitted with the redetermination request.

(a) *Evidence submitted with the request.* When filing the request for redetermination, a party must explain why it disagrees with the contractor's determination and should include any evidence that the party believes should be considered by the contractor in making its redetermination.

(b) *Evidence submitted after the request.* When a party submits additional evidence after filing the request for redetermination, the contractor's 60-day decision-making time frame is automatically extended for up to 14 calendar days for each submission.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

§ 405.948 Conduct of a redetermination.

A redetermination consists of an independent review of an initial determination. In conducting a redetermination, the contractor reviews the evidence and findings upon which the initial determination was based, and any additional evidence the parties submit or the contractor obtains on its own. An individual who was not involved in making the initial determination must make a redetermination. The contractor may raise and develop new issues that are relevant to the claims in the particular case.

§ 405.950 Time frame for making a redetermination.

(a) *General rule.* The contractor mails, or otherwise transmits, written notice of the redetermination or dismissal to the parties to the redetermination at their last known addresses within 60 calendar days of the date the contractor receives a timely filed request for redetermination.

(b) *Exceptions.* (1) If a contractor grants an appellant's request for an extension of the 120-day filing deadline made in accordance with § 405.942(b), the 60-day decision-making time frame begins on the date the contractor receives the late-filed request for redetermination, or when the request for an extension is granted, whichever is later.

(2) If a contractor receives from multiple parties timely requests for redetermination of a claim determination, consistent with § 405.944(c), the contractor must issue a redetermination or dismissal within 60 days of the latest filed request.

(3) If a party submits additional evidence after the request for redetermination is filed, the contractor's 60-day decision-making time frame is extended for up to 14 calendar days for each submission, consistent with § 405.946(b).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

§ 405.952 Withdrawal or dismissal of a request for a redetermination.

(a) *Withdrawing a request.* A party that files a request for redetermination may withdraw its request by filing a written and signed request for withdrawal. The request for withdrawal must contain a clear statement that the appellant is withdrawing the request for a redetermination and does not intend to proceed further with the appeal. The request must be received in the contractor's mailroom before a redetermination is issued. The appeal will proceed with respect to any other parties that have filed a timely request for redetermination.

(b) *Dismissing a request.* A contractor dismisses a redetermination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a redetermination is not a proper party under § 405.906(b) or does not otherwise have a right to a redetermination under section 1869(a) of the Act;

(2) When the contractor determines the party failed to make out a valid request for redetermination that substantially complies with § 405.944;

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with § 405.942;

(4) When a beneficiary or the beneficiary's representative files a request for redetermination, but the beneficiary dies while the request is pending, and all of the following criteria apply:

(i) The beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the contractor considers if the surviving spouse or estate remains liable for the services for which payment was denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of payment for services at issue;

(ii) No other individual or entity with a financial interest in the case wishes to pursue the appeal; and

(iii) No other party filed a valid and timely redetermination request under § 405.942 and § 405.944;

(5) When a party filing the redetermination request submits a timely written request for withdrawal with the contractor; or

(6) When the contractor has not issued an initial determination on the claim or the matter for which a redetermination is sought.

(c) *Notice of dismissal.* A contractor mails or otherwise transmits a written notice of the dismissal of the redetermination request to the parties at their last known addresses. The notice states that there is a right to request that the contractor vacate the dismissal action.

(d) *Vacating a dismissal.* If good and sufficient cause is established, a contractor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(e) *Effect of dismissal.* The dismissal of a request for redetermination is final and binding, unless it is modified or reversed by a QIC under § 405.974(b) or vacated under paragraph (d) of this section.

§ 405.954 Redetermination.

Upon the basis of the evidence of record, the contractor adjudicates the claim(s), and renders a redetermination affirming or reversing, in whole or in part, the initial determination in question.

§ 405.956 Notice of a redetermination.

(a) *Notification to parties.* (1) *General rule.* Written notice of a redetermination affirming, in whole or in part, the

initial determination must be mailed or otherwise transmitted to all parties at their last known addresses in accordance with the time frames established in § 405.950. Written notice of a redetermination fully reversing the initial determination must be mailed or otherwise transmitted to the appellant in accordance with the time frames established in § 405.950. If the redetermination results in issuance of supplemental payment to a provider or supplier, the Medicare contractor must also issue an electronic or paper RA notice to the provider or supplier.

(2) *Overpayment cases involving multiple beneficiaries who have no liability.* In an overpayment case involving multiple beneficiaries who have no liability, the contractor may issue a written notice only to the appellant.

(b) *Content of the notice for affirmations, in whole or in part.* For decisions that are affirmations, in whole or in part, of the initial determination, the redetermination must be written in a manner calculated to be understood by a beneficiary, and contain—

(1) A clear statement indicating the extent to which the redetermination is favorable or unfavorable;

(2) A summary of the facts, including, as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(3) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case;

(4) A summary of the rationale for the redetermination in clear, understandable language;

(5) Notification to the parties of their right to a reconsideration and a description of the procedures that a party must follow in order to request a reconsideration, including the time frame within which a reconsideration must be requested;

(6) A statement of any specific missing documentation that must be submitted with a request for a reconsideration, if applicable;

(7) A statement that all evidence the appellant wishes to introduce during the claim appeals process should be submitted with the request for a reconsideration;

(8) Notification that evidence not submitted to the QIC as indicated in paragraph (b)(6) of this section, is not considered at an ALJ hearing or further appeal, unless the appellant demonstrates good cause as to why that evidence was not provided previously; and

(9) The procedures for obtaining additional information concerning the redetermination, such as specific provisions of the policy, manual, or regulation used in making the redetermination.

(10) Any other requirements specified by CMS.

(c) *Content of the notice for a full reversal.* For decisions that are full reversals of the initial determination, the redetermination must be in writing and contain—

(1) A clear statement indicating that the redetermination is wholly favorable;

(2) Any other requirements specified by CMS.

(d) *Exception for beneficiary appeal requests.* (1) The notice must inform beneficiary appellants that the requirements of paragraph (b)(8) of this section are not applicable for purposes of beneficiary appeals.

(2) This exception does not apply for appeal requests from beneficiaries who are represented by providers or suppliers.

§ 405.958 Effect of a redetermination.

In accordance with section 1869 (a)(3)(D) of the Act, once a redetermination is issued, it becomes part of the initial determination. The redetermination is final and binding upon all parties unless—

(a) A reconsideration is completed in accordance with § 405.960 through § 405.978; or

(b) The redetermination is revised as a result of a reopening in accordance with § 405.980.

RECONSIDERATION

§ 405.960 Right to a reconsideration.

A person or entity that is a party to a redetermination made by a contractor as described under § 405.940 through § 405.958, and is dissatisfied with that determination, may request

a reconsideration by a QIC in accordance with § 405.962 through § 405.966, regardless of the amount in controversy.

§ 405.962 Timeframe for filing a request for a reconsideration.

(a) *Timeframe for filing a request.* Except as provided in paragraph (b) of this section, any request for a reconsideration must be filed within 180 calendar days from the date the party receives the notice of the redetermination.

(1) For purposes of this section, the date of receipt of the redetermination will be presumed to be 5 days after the date of the notice of redetermination, unless there is evidence to the contrary.

(2) For purposes of meeting the 180-day filing deadline, the request is considered as filed on the date it is received by the QIC.

(b) *Extending the time for filing a request.* (1) *General rule.* A QIC may extend the 180-day timeframe for filing a request for reconsideration for good cause.

(2) *How to request an extension.* A party to the redetermination must file its request for an extension of the time for filing the reconsideration request with its request for reconsideration. A party should include evidence to support the request for extension. The request for reconsideration and request for extension must—

(i) Be in writing;

(ii) State why the request for reconsideration was not filed within the required timeframe; and

(iii) Meet the requirements of § 405.964.

(3) *How the QIC determines whether good cause exists.* In determining whether a party has good cause for missing a deadline to request reconsideration, the QIC applies the good cause provisions contained in § 405.942(b)(2) and (b)(3).

§ 405.964 Place and method of filing a request for a reconsideration.

(a) *Filing location.* The request for reconsideration must be filed with the QIC indicated on the notice of redetermination.

(b) *Content of reconsideration request.* The request for reconsideration must be in writing and should be made on a standard CMS form. A written request that is not made on a standard CMS form is accepted if it contains the same required elements, as follows:

(1) The beneficiary's name;

(2) Medicare health insurance claim number;

(3) Specific service(s) and item(s) for which the reconsideration is requested and the specific date(s) of service;

(4) The name and signature of the party or the representative of the party; and

(5) The name of the contractor that made the redetermination.

(c) *Requests for reconsideration by more than one party.* If more than one party timely files a request for reconsideration on the same claim before a reconsideration is made on the first timely filed request, the QIC must consolidate the separate requests into one proceeding and issue one reconsideration.

§ 405.966 Evidence to be submitted with the reconsideration request.

(a) *Evidence submitted with the request.* When filing a request for reconsideration, a party should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination, including the redetermination.

(1) This evidence must include any missing documentation identified in the notice of redetermination, consistent with § 405.956(b)(6).

(2) Absent good cause, failure to submit all evidence, including documentation requested in the notice of redetermination prior to the issuance of the notice of reconsideration precludes subsequent consideration of that evidence.

(b) *Evidence submitted after the request.* Each time a party submits additional evidence after filing the request for reconsideration, the QIC's 60-day decisionmaking timeframe is automatically extended by up to 14 calendar days for each submission. This extension does not apply to timely submissions of documentation specifically requested by a QIC, unless the documentation was originally requested in the notice of redetermination.

(c) *Exception for beneficiaries and State Medicaid Agencies that file reconsideration requests.* (1) Beneficiaries and State Medicaid Agencies that file requests for reconsideration are not required to comply with the requirements of paragraph (a) of this section. However, the automatic 14-day extension described in paragraph (b) of this section applies to each evidence submission made after the request for reconsideration is filed.

(2) Beneficiaries who are represented by providers or suppliers must comply with the requirements of paragraph (a) of this section.

§ 405.968 Conduct of a reconsideration.

(a) *General rules.* (1) A reconsideration consists of an independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim. In conducting a reconsideration, the QIC reviews the evidence and findings upon which the initial determination, including the redetermination, was based, and any additional evidence the parties submit or that the QIC obtains on its own. If the initial determination involves a finding on whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) of the Act), a QIC's reconsideration must involve consideration by a panel of physicians or other appropriate health care professionals, and be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence of record to the extent applicable.

(b) *Authority of the QIC.* (1) National coverage determinations (NCDs), CMS Rulings, and applicable laws and regulations are binding on the QIC.

(2) QICs are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but give substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines, either at a party's request or at its own discretion, that the policy does not apply to the facts of the particular case.

(3) If a QIC declines to follow a policy in a particular case, the QIC's reconsideration explains the reasons why the policy was not followed.

(4) A QIC's decision to decline to follow a policy under this section applies only to the specific claim being reconsidered and does not have precedential effect.

(5) A QIC may raise and develop new issues that are relevant to the claims in a particular case provided that the contractor rendered a redetermination with respect to the claims.

(c) *Qualifications of the QIC's panel members.* (1) Members of a QIC's panel who conduct reconsiderations must have sufficient medical, legal, and other expertise, including knowledge of the Medicare program.

(2) When a redetermination is made with respect to whether an item or service is reasonable and necessary (section 1862(a)(1)(A) of the Act), the QIC designates a panel of physicians or other appropriate health care professionals to consider the facts and circumstances of the redetermination.

(3) Where a claim pertains to the furnishing of treatment by a physician, or the provision of items or services by a physician, a reviewing professional must be a physician.

(d) *Disqualification of a QIC panel member.* No physician or health care professional employed by or otherwise working for a QIC may review determinations regarding—

(1) Health care services furnished to a patient if that physician or health care professional was directly responsible for furnishing those services; or

(2) Health care services provided in or by an institution, organization, or agency, if that physician or health care professional or any member of the physician's family or health care professional's family has, directly or indirectly, a significant financial interest in that institution, organization, or agency (see the term family member as defined in § 405.902).

§ 405.970 Timeframe for making a reconsideration.

(a) *General rule.* Within 60 calendar days of the date the QIC receives a timely filed request for reconsideration or any additional time provided by

paragraph (b) of this section, the QIC mails, or otherwise transmits to the parties at their last known addresses, written notice of—

(1) The reconsideration;

(2) Its inability to complete its review within 60 days in accordance with paragraphs (c) through (e) of this section; or

(3) Dismissal.

(b) *Exceptions.* (1) If a QIC grants an appellant's request for an extension of the 180-day filing deadline made in accordance with § 405.962(b), the QIC's 60-day decision-making timeframe begins on the date the QIC receives the late filed request for reconsideration, or when the request for an extension that meets the requirements of § 405.962(b) is granted, whichever is later.

(2) If a QIC receives timely requests for reconsideration from multiple parties, consistent with § 405.964(c), the QIC must issue a reconsideration, notice that it cannot complete its review, or dismissal within 60 days for each submission of the latest filed request.

(3) Each time a party submits additional evidence after the request for reconsideration is filed, the QIC's 60-day decisionmaking timeframe is extended by up to 14 days for each submission, consistent with § 405.966(b).

(c) *Responsibilities of the QIC.* Within 60 days of receiving a request for a reconsideration, or any additional time provided for under paragraph (b) of this section, a QIC must take one of the following actions:

(1) Notify all parties of its reconsideration, consistent with § 405.976.

(2) Notify the parties that it cannot complete the reconsideration by the deadline specified in paragraph (b) of this section and offer the appellant the opportunity to escalate the appeal to an ALJ. The QIC continues to process the reconsideration unless it receives a written request from the appellant to escalate the case to an ALJ after the adjudication period has expired.

(d) *Responsibilities of the appellant.* If an appellant wishes to exercise the option of escalating the case to an ALJ, the appellant must notify the QIC in writing.

(e) *Actions following appellant's notice.* (1) If the appellant fails to notify the QIC, or notifies the QIC that the appellant does not choose to escalate the case, the QIC completes its reconsideration and notifies the appellant of its action consistent with § 405.972 or § 405.976.

(2) If the appellant notifies the QIC that the appellant wishes to escalate the case, the QIC must take one of the following actions within 5 days of receipt of the notice or 5 days from the end of the applicable adjudication period under paragraph (a) or (b) of this section:

(i) Complete its reconsideration and notify all parties of its decision consistent with § 405.972 or § 405.976.

(ii) Acknowledge the escalation notice in writing and forward the case file to the ALJ hearing office.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

§ 405.972 Withdrawal or dismissal of a request for a reconsideration.

(a) *Withdrawing a request.* An appellant that files a request for reconsideration may withdraw its request by filing a written and signed request for withdrawal. The request for withdrawal must—

(1) Contain a clear statement that the appellant is withdrawing the request for reconsideration and does not intend to proceed further with the appeal.

(2) Be received in the QIC's mailroom before the reconsideration is issued.

(b) *Dismissing a request.* A QIC dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting reconsideration is not a proper party under § 405.906(b) or does not otherwise have a right to a reconsideration under section 1869(b) of the Act;

(2) When the QIC determines that the party failed to make out a valid request for reconsideration that substantially complies with § 405.964(a) and (b);

(3) When the party fails to file the reconsideration request in accordance with the timeframes established in § 405.962;

(4) When a beneficiary or the beneficiary's representative files a request for reconsideration, but the beneficiary

dies while the request is pending, and all of the following criteria apply:

(i) The beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the QIC considers if the surviving spouse or estate remains liable for the services for which payment was denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of payment for services at issue;

(ii) No other individual or entity with a financial interest in the case wishes to pursue the appeal; and

(iii) No other party to the redetermination filed a valid and timely request for reconsideration under § 405.962 and § 405.964.

(5) When a party filing for the reconsideration submits a written request of withdrawal to the QIC and satisfies the criteria set forth in paragraph (a) of this section before the reconsideration has been issued; or

(6) When the contractor has not issued a redetermination on the initial determination for which a reconsideration is sought.

(c) *Notice of dismissal.* A QIC mails or otherwise transmits written notice of the dismissal of the reconsideration request to the parties at their last known addresses. The notice states that there is a right to request that the contractor vacate the dismissal action. The appeal will proceed with respect to any other parties that have filed a timely request for reconsideration.

(d) *Vacating a dismissal.* If good and sufficient cause is established, a QIC may vacate its dismissal of a request for reconsideration within 6 months of the date of the notice of dismissal.

(e) *Effect of dismissal.* The dismissal of a request for reconsideration is final and binding, unless it is modified or reversed by an ALJ under § 405.1004 or vacated under paragraph (d) of this section.

§ 405.974 Reconsideration.

(a) *Reconsideration of a contractor determination.* Except as provided in § 405.972, upon the basis of the evidence of record, the QIC must issue a reconsideration affirming or reversing, in whole or in part, the initial determination, including the redetermination, in question.

(b) *Reconsideration of contractor's dismissal of a redetermination request.* (1) A party to a contractor's dismissal of a request for redetermination has a right to have the dismissal reviewed by a QIC, if the party files a written request for review of the dismissal with the QIC within 60 days after receipt of the contractor's notice of dismissal.

(i) For purposes of this section, the date of receipt of the contractor's notice of dismissal is presumed to be 5 days after the date of the notice of dismissal, unless there is evidence to the contrary.

(ii) For purposes of meeting the 60-day filing deadline, the request is considered as filed on the date it is received by the QIC indicated on the notice of dismissal.

(2) If the QIC determines that the contractor's dismissal was in error, it vacates the dismissal and remands the case to the contractor for a redetermination.

(3) A QIC's reconsideration of a contractor's dismissal of a redetermination request is final and not subject to any further review.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§ 405.976 Notice of a reconsideration.

(a) *Notification to parties.* (1) *General rules.* (i) Written notice of the reconsideration must be mailed or otherwise transmitted to all parties at their last known addresses, in accordance with the timeframes established in § 405.970(a) or (b).

(ii) The notice must be written in a manner reasonably calculated to be understood by a beneficiary.

(iii) The QIC must promptly notify the entity responsible for payment of claims under Part A or Part B of its reconsideration. If the reconsideration results in issuance of supplemental payment to a provider or supplier, the Medicare contractor must also issue an electronic or paper RA notice to the provider or supplier.

(2) *Overpayment cases involving multiple beneficiaries who have no liability.*

In an overpayment case involving multiple beneficiaries who have no liability, the QIC may issue a written notice only to the appellant.

(b) *Content of the notice.* The reconsideration must be in writing and contain—

(1) A clear statement indicating whether the reconsideration is favorable or unfavorable;

(2) A summary of the facts, including as appropriate, a summary of the clinical or scientific evidence used in making the reconsideration;

(3) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies, apply to the facts of the case, including, where applicable, the rationale for declining to follow an LCD, LMRP, or CMS program guidance;

(4) In the case of a determination on whether an item or service is reasonable or necessary under section 1862(a)(1)(A) of the Act, an explanation of the medical and scientific rationale for the decision;

(5) A summary of the rationale for the reconsideration.

(i) If the notice of redetermination indicated that specific documentation should be submitted with the reconsideration request, and the documentation was not submitted with the request for reconsideration, the summary must indicate how the missing documentation affected the reconsideration; and

(ii) The summary must also specify that, consistent with § 405.956(b)(8) and § 405.966(b), all evidence, including evidence requested in the notice of redetermination, that is not submitted prior to the issuance of the reconsideration will not be considered at an ALJ level, or made part of the administrative record, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration. This requirement does not apply to beneficiaries, unless the beneficiary is represented by a provider or supplier or to State Medicaid Agencies;

(6) Information concerning to the parties' right to an ALJ hearing, including the applicable amount in controversy requirement and aggregation provisions;

(7) A statement of whether the amount in controversy needed for an ALJ hearing is met when the reconsideration is partially or fully unfavorable;

(8) A description of the procedures that a party must follow in order to obtain an ALJ hearing of an expedited reconsideration, including the time frame under which a request for an ALJ hearing must be filed;

(9) If appropriate, advice as to the requirements for use of the expedited access to judicial review process set forth in § 405.990;

(10) The procedures for obtaining additional information concerning the reconsideration, such as specific provisions of the policy, manual, or regulation used in making the reconsideration; and

(11) Any other requirements specified by CMS.

§ 405.978 Effect of a reconsideration.

A reconsideration is final and binding on all parties, unless—

(a) An ALJ decision is issued in accordance to a request for an ALJ hearing made in accordance with § 405.1014;

(b) A review entity issues a decision in accordance to a request for expedited access to judicial review under § 405.990; or

(c) The reconsideration is revised as a result of a reopening in accordance with § 405.980.

REOPENINGS

§ 405.980 Reopenings of initial determinations, redeterminations, and reconsiderations, hearings and reviews.

(a) *General rules.* (1) A reopening is a remedial action taken to change a final determination or decision that resulted in either an overpayment or underpayment, even though the final determination or decision may have been correct at the time it was made based on the evidence of record. That action may be taken by—

(i) A contractor to revise the initial determination or redetermination;

(ii) A QIC to revise the reconsideration;

(iii) An ALJ to revise the hearing decision; or

(iv) The MAC to revise the hearing or review decision.

(2) If a contractor issues a denial of a claim because it did not receive requested documentation during medical review and the party subsequently requests a redetermination, the contractor must process the request as a reopening.

(3) Notwithstanding paragraph (a)(4) of this section, a contractor must process clerical errors (which includes minor errors and omissions) as reopenings, instead of as redeterminations as specified in § 405.940. If the contractor receives a request for reopening and disagrees that the issue is a clerical error, the contractor must dismiss the reopening request and advise the party of any appeal rights, provided the timeframe to request an appeal on the original denial has not expired. For purposes of this section, clerical error includes human or mechanical errors on the part of the party or the contractor such as—

(i) Mathematical or computational mistakes;

(ii) Inaccurate data entry; or

(iii) Denials of claims as duplicates.

(4) When a party has filed a valid request for an appeal of an initial determination, redetermination, reconsideration, hearing, or MAC review, no adjudicator has jurisdiction to reopen an issue on a claim that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the contractor, QIC, ALJ, or MAC may reopen as set forth in this section.

(5) The contractor's, QIC's, ALJ's, or MAC's decision on whether to reopen is final and not subject to appeal.

(6) A determination under the Medicare secondary payer provisions of section 1862(b) of the Act that Medicare has an MSP recovery claim for services or items that were already reimbursed by the Medicare program is not a reopening, except where the recovery claim is based upon a provider's or supplier's failure to demonstrate that it filed a proper claim as defined in part 411 of this chapter.

(b) *Time frames and requirements for reopening initial determinations and redeterminations initiated by a contractor.* A contractor may reopen and revise its initial determination or redetermination on its own motion—

(1) Within 1 year from the date of the initial determination or redetermination for any reason.

(2) Within 4 years from the date of the initial determination or redetermination for good cause as defined in § 405.986.

(3) At any time if there exists reliable evidence as defined in § 405.902 that the initial determination was procured by fraud or similar fault as defined in § 405.902.

(4) At anytime if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based.

(5) At any time to effectuate a decision issued under the coverage appeals process.

(c) *Time frame and requirements for reopening initial determinations and redeterminations requested by a party.* (1) A party may request that a contractor reopen its initial determination or redetermination within 1 year from the date of the initial determination or redetermination for any reason.

(2) A party may request that a contractor reopen its initial determination or redetermination within 4 years from the date of the initial determination or redetermination for good cause in accordance with § 405.986.

(3) A party may request that a contractor reopen its initial determination at any time if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based. Third party payer error does not constitute clerical error. *See* § 405.986(c).

(d) *Time frame and requirements for reopening reconsiderations, hearing decisions and reviews initiated by a QIC, ALJ, or the MAC.* (1) A QIC may reopen its reconsideration on its own motion within 180 days from the date of the reconsideration for good cause in accordance with § 405.986. If the QIC's reconsideration was procured by fraud or similar fault, then the QIC may reopen at any time.

(2) An ALJ or the MAC may reopen a hearing decision on its own motion

within 180 days from the date of the decision for good cause in accordance with § 405.986. If the hearing decision was procured by fraud or similar fault, then the ALJ or the MAC may reopen at any time.

(3) The MAC may reopen its review decision on its own motion within 180 days from the date of the review decision for good cause in accordance with § 405.986. If the MAC's decision was procured by fraud or similar fault, then the MAC may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, hearing decisions, and reviews requested by a party.* (1) A party to a reconsideration may request that a QIC reopen its reconsideration within 180 days from the date of the reconsideration for good cause in accordance with § 405.986.

(2) A party to a hearing may request that an ALJ or the MAC reopen a hearing decision within 180 days from the date of the hearing decision for good cause in accordance with § 405.986.

(3) A party to a review may request that the MAC reopen its decision within 180 days from the date of the review decision for good cause in accordance with § 405.986.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§ 405.982 Notice of a revised determination or decision.

(a) *When adjudicators initiate reopenings.* When any determination or decision is reopened and revised as provided in § 405.980, the contractor, QIC, ALJ, or the MAC must mail its revised determination or decision to the parties to that determination or decision at their last known address. In the case of a full or partial reversal resulting in issuance of a payment to a provider or supplier, a revised electronic or paper remittance advice notice must be issued by the Medicare contractor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

(b) *Reopenings initiated at the request of a party.* The contractor, QIC, ALJ, or the MAC must mail its revised determination or decision to the parties to that determination or decision at their last known address. In the case of a full or partial reversal resulting in issuance of a payment to a provider or supplier, a revised electronic or paper remittance advice notice must be issued by the Medicare contractor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

§ 405.984 Effect of a revised determination or decision.

(a) *Initial determinations.* The revision of an initial determination is binding upon all parties unless a party files a written request for a redetermination that is accepted and processed in accordance with § 405.940 through § 405.958.

(b) *Redeterminations.* The revision of a redetermination is binding upon all parties unless a party files a written request for a QIC reconsideration that is accepted and processed in accordance with § 405.960 through § 405.978.

(c) *Reconsiderations.* The revision of a reconsideration is binding upon all parties unless a party files a written request for an ALJ hearing that is accepted and processed in accordance with § 405.1000 through § 405.1064.

(d) *ALJ Hearing decisions.* The revision of a hearing decision is binding upon all parties unless a party files a written request for a MAC review that is accepted and processed in accordance with § 405.1100 through § 405.1130.

(e) *MAC review.* The revision of a MAC review is binding upon all parties unless a party files a civil action in which a Federal district court accepts jurisdiction and issues a decision.

(f) *Appeal of only the portion of the determination or decision revised by the reopening.* Only the portion of the initial determination, redetermination, reconsideration, or hearing decision revised by the reopening may be subsequently appealed.

(g) *Effect of a revised determination or decision.* A revised determination or decision is binding unless it is appealed or otherwise reopened.

§ 405.986 Good cause for reopening.

(a) *Establishing good cause.* Good cause may be established when—

(1) There is new and material evidence that—

(i) Was not available or known at the time of the determination or decision; and

(ii) May result in a different conclusion; or

(2) The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

(b) *Change in substantive law or interpretative policy*. A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, or a change in legal interpretation or policy by SSA in a regulation, SSA ruling, or SSA general instruction in entitlement appeals, whether made in response to judicial precedent or otherwise, is not a basis for reopening a determination or hearing decision under this section. This provision does not preclude contractors from conducting reopenings to effectuate coverage decisions issued under the authority granted by section 1869(f) of the Act.

(c) *Third party payer error*. A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

EXPEDITED ACCESS TO JUDICIAL REVIEW

§ 405.990 Expedited access to judicial review.

(a) *Process for expedited access to judicial review*. (1) For purposes of this section, a ''review entity'' means an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board (DAB), as determined by the Secretary.

(2) In order to obtain expedited access to judicial review (EAJR), a review entity must certify that the Medicare Appeals Council (MAC) does not have the authority to decide the question of law or regulation relevant to the matters in dispute and that there is no material issue of fact in dispute.

(3) A party may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

(b) *Conditions for making the expedited appeals request*. (1) A party may request EAJR in place of an ALJ hearing or MAC review if the following conditions are met:

(i) A QIC has made a reconsideration determination and the party has filed a request for—

(A) An ALJ hearing in accordance with § 405.1002 and a final decision of the ALJ has not been issued;

(B) MAC review in accordance with § 405.1102 and a final decision of the MAC has not been issued; or

(ii) The appeal has been escalated from the QIC to the ALJ level after the period described in § 405.970(a) and § 405.970(b) has expired, and the QIC does not issue a final action within the time frame described in § 405.970(e).

(2) The requestor is a party, as defined in paragraph (e) of this section.

(3) The amount remaining in controversy meets the requirements of § 405.1006(b) or (c).

(4) If there is more than one party to the reconsideration, hearing, or MAC review, each party concurs, in writing, with the request for the EAJR.

(5) There are no material issues of fact in dispute.

(c) *Content of the request for EAJR*. The request for EAJR must—

(1) Allege that there are no material issues of fact in dispute and identify the facts that the requestor considers material and that are not disputed; and

(2) Assert that the only factor precluding a decision favorable to the requestor is—

(i) A statutory provision that is unconstitutional, or a provision of a regulation or national coverage determination and specify the statutory provision that the requestor considers unconstitutional or the provision of a regulation or a national coverage determination that the requestor considers invalid, or

(ii) A CMS Ruling that the requester considers invalid;

(3) Include a copy of any QIC reconsideration and of any ALJ hearing decision that the requester has received;

(4) If any QIC reconsideration or ALJ hearing decision was based on facts that the requestor is disputing, state why the requestor considers those facts to be immaterial; and

(5) If any QIC reconsideration or ALJ hearing decision was based on a provision of a law, regulation, national coverage determination or CMS Ruling in addition to the one the requestor considers unconstitutional or invalid, a statement as to why further administrative review of how that provision applies to the facts is not necessary.

(d) *Place and time for an EAJR request.* (1) *Method and place for filing request.* The requestor may include an EAJR request in his or her request for an ALJ hearing or MAC review, or, if an appeal is already pending with an ALJ or the MAC, file a written EAJR request with the ALJ hearing office or MAC where the appeal is being considered. The ALJ hearing office or MAC forwards the request to the review entity within 5 calendar days of receipt.

(2) *Time of filing request.* The party may file a request for the EAJR—

(i) If the party has requested a hearing, at any time before receipt of the notice of the ALJ's decision; or

(ii) If the party has requested MAC review, at any time before receipt of notice of the MAC's decision.

(e) *Parties to the EAJR.* The parties to the EAJR are the persons or entities who were parties to the QIC's reconsideration determination and, if applicable, to the ALJ hearing.

(f) *Determination on EAJR request.* (1) The review entity described in paragraph (a) of this section will determine whether the request for EAJR meets all of the requirements of paragraphs (b), (c), and (d) of this section.

(2) Within 60 days after the date the review entity receives a request and accompanying documents and materials meeting the conditions in paragraphs (b), (c), and (d) of this section, the review entity will issue either a certification in accordance to paragraph (g) of this section or a denial of the request.

(3) A determination by the review entity either certifying that the requirements for EAJR are met pursuant to paragraph (g) of this section or denying the request is final and not subject to review by the Secretary.

(4) If the review entity fails to make a determination within the time frame specified in paragraph (f)(2) of this section, then the requestor may bring a civil action in Federal district court within 60 days of the end of the time frame.

(g) *Certification by the review entity.* If a party meets the requirements for the EAJR, the review entity certifies in writing that—

(1) The material facts involved in the claim are not in dispute;

(2) Except as indicated in paragraph (g)(3) of this section, the Secretary's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision, or the validity of a provision of a regulation, CMS Ruling, or national coverage determination;

(4) But for the provision challenged, the requestor would receive a favorable decision on the ultimate issue (such as whether a claim should be paid); and

(5) The certification by the review entity is the Secretary's final action for purposes of seeking expedited judicial review.

(h) *Effect of certification by the review entity.* If an EAJR request results in a certification described in paragraph (g) of this section—

(1) The party that requested the EAJR is considered to have waived any right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

(2) The requestor has 60 days, beginning on the date of the review entity's certification within which to bring a civil action in Federal district court.

(3) The requestor must satisfy the requirements for venue under section 1869(b)(2)(C)(iii) of the Act, as well as the requirements for filing a civil action in a Federal district court under §405.1136(a) and §405.1136(c) through §405.1136(f).

(i) *Rejection of EAJR.* (1) If a request for EAJR request does not meet all the conditions set out in paragraphs (b), (c) and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises in writing all parties that the request has

been denied, and returns the request to the ALJ hearing office or the MAC, which will treat it as a request for hearing or for MAC review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to an ALJ hearing office or the MAC, the appeal is considered timely filed and the 90-day decision making time frame begins on the day the request is received by the hearing office or the MAC.

(j) *Interest on any amounts in controversy.* (1) If a provider or supplier is granted judicial review in accordance with this section, the amount in controversy, if any, is subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined in accordance with paragraphs (f)(4) or (h)(2) of this section, as applicable.

(2) The interest is awarded by the reviewing court and payable to a prevailing party.

(3) The rate of interest is equal to the rate of interest applicable to obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this subpart is commenced.

(4) No interest awarded in accordance with this paragraph shall be income or cost for purposes of determining reimbursement due to providers or suppliers under Medicare.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

ALJ HEARINGS

§ 405.1000 Hearing before an ALJ: General rule.

(a) If a party is dissatisfied with a QIC's reconsideration or if the adjudication period specified in § 405.970 for the QIC to complete its reconsideration has elapsed, the party may request a hearing.

(b) A hearing may be conducted in-person, by video-teleconference (VTC), or by telephone. At the hearing, the parties may submit evidence (subject to the restrictions in § 405.1018 and § 405.1028), examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, a representative of CMS or its contractor, including the QIC, QIO, fiscal intermediary or carrier, may participate in or join the hearing as a party. (*see* § 405.1010 and § 405.1012).

(d) The ALJ issues a decision based on the hearing record.

(e) If all parties to the hearing waive their right to appear at the hearing in person or by telephone or video-teleconference, the ALJ may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the parties to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In that event, however, the ALJ will give the parties the opportunity to appear when the testimony is given, but may hold the hearing even if none of the parties decide to appear.

(g) An ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding.

§ 405.1002 Right to an ALJ hearing.

(a) A party to a QIC reconsideration may request a hearing before an ALJ if—

(1) The party files a written request for an ALJ hearing within 60 days after receipt of the notice of the QIC's reconsideration.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 days after the date of the reconsideration, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-day filing deadline, the request is considered as filed on the date it is received by the entity specified in the QIC's reconsideration.

(b) A party who files a timely appeal before a QIC and whose appeal continues to be pending before a QIC at the end of the period described in

§405.970 has a right to a hearing before an ALJ if—

(1) The party files a written request with the QIC to escalate the appeal to the ALJ level after the period described in §405.970(a) and (b) has expired and the party files the request in accordance with §405.970(d);

(2) The QIC does not issue a final action within 5 days of receiving the request for escalation in accordance with §405.970(e)(2); and

(3) The party has an amount remaining in controversy specified in §405.1006.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§405.1004 Right to ALJ review of QIC notice of dismissal.

(a) A party to a QIC's dismissal of a request for reconsideration has a right to have the dismissal reviewed by an ALJ if—

(1) The party files a written request for an ALJ review within 60 days after receipt of the notice of the QIC's dismissal.

(2) The party meets the amount in controversy requirements of §405.1006.

(3) For purposes of this section, the date of receipt of the QIC's dismissal is presumed to be 5 days after the date of the dismissal notice, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-day filing deadline, the request is considered as filed on the date it is received by the entity specified in the QIC's dismissal.

(b) If the ALJ determines that the QIC's dismissal was in error, he or she vacates the dismissal and remands the case to the QIC for a reconsideration.

(c) An ALJ's decision regarding a QIC's dismissal of a reconsideration request is final and not subject to further review.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§405.1006 Amount in controversy required to request an ALJ hearing and judicial review.

(a) *Definitions.* For the purposes of aggregating claims to meet the amount in controversy requirement for an ALJ hearing or judicial review:

(1) ''Common issues of law and fact'' means the claims sought to be aggregated are denied, or payment is reduced, for similar reasons and arise from a similar fact pattern material to the reason the claims are denied or payment is reduced.

(2) ''Delivery of similar or related services'' means like or coordinated services or items provided to one or more beneficiaries.

(b) *ALJ review.* To be entitled to a hearing before an ALJ, the party must meet the amount in controversy requirements of this section.

(1) For ALJ hearing requests, the required amount remaining in controversy must be $100 increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) as measured from July 2003 to the July preceding the current year involved.

(2) If the figure in paragraph (b)(1) of this section is not a multiple of $10, then it is rounded to the nearest multiple of $10. The Secretary will publish changes to the amount in controversy requirement in the FEDERAL REGISTER when necessary.

(c) *Judicial review.* To be entitled to judicial review, a party must meet the amount in controversy requirements of this subpart at the time it requests judicial review.

(1) For review requests, the required amount remaining in controversy must be $1,000 or more, adjusted as specified in paragraphs (b)(1) and (b)(2) of this section.

(2) [Reserved]

(d) *Calculating the amount remaining in controversy.* (1) The amount remaining in controversy is computed as the actual amount charged the individual for the items and services in question, reduced by—

(i) Any Medicare payments already made or awarded for the items or services; and

(ii) Any deductible and coinsurance amounts applicable in the particular case.

(2) Notwithstanding paragraph (d)(1) of this section, when payment is made for items or services under section 1879 of the Act or §411.400 of this chapter, or the liability of the beneficiary for

those services is limited under § 411.402 of this chapter, the amount in controversy is computed as the amount that the beneficiary would have been charged for the items or services in question if those expenses were not paid under § 411.400 of this chapter or if that liability was not limited under § 411.402 of this chapter, reduced by any deductible and coinsurance amounts applicable in the particular case.

(e) *Aggregating claims to meet the amount in controversy—*

(1) *Appealing QIC reconsiderations to the ALJ level.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were previously reconsidered by a QIC;

(ii) The request for ALJ hearing lists all of the claims to be aggregated and is filed within 60 days after receipt of all of the reconsiderations being appealed; and

(iii) The ALJ determines that the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(2) *Aggregating claims that are escalated from the QIC level to the ALJ level.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were pending before the QIC in conjunction with the same request for reconsideration;

(ii) The appellant(s) requests aggregation of the claims to the ALJ level in the same request for escalation; and

(iii) The ALJ determines that the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(f) *Content of request for aggregation.* When an appellant(s) seeks to aggregate claims in a request for an ALJ hearing, the appellant(s) must—

(1) Specify all of the claims the appellant(s) seeks to aggregate; and

(2) State why the appellant(s) believes that the claims involve common issues of law and fact or delivery of similar or related services.

§ 405.1008 Parties to an ALJ hearing.

(a) *Who may request a hearing.* Any party to the QIC's reconsideration may request a hearing before an ALJ. However, only the appellant (that is, the party that filed and maintained the request for reconsideration by a QIC) may request that the appeal be escalated to the ALJ level if the QIC does not complete its action within the time frame described in § 405.970.

(b) *Who are parties to the ALJ hearing.* The party who filed the request for hearing and all other parties to the reconsideration are parties to the ALJ hearing. In addition, a representative of CMS or its contractor may be a party under the circumstances described in § 405.1012.

§ 405.1010 When CMS or its contractors may participate in an ALJ hearing.

(a) An ALJ may request, but may not require, CMS and/or one or more of its contractors, to participate in any proceedings before the ALJ, including the oral hearing, if any. CMS and/or one or more of its contractors, including a QIC, may also elect to participate in the hearing process.

(b) If CMS or one or more of its contractors elects to participate, it advises the ALJ, the appellant, and all other parties identified in the notice of hearing of its intent to participate no later than 10 days after receiving the notice of hearing.

(c) Participation may include filing position papers or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of a party to the hearing.

(d) When CMS or its contractor participates in an ALJ hearing, the agency or its contractor may not be called as a witness during the hearing.

(e) CMS or its contractor must submit any position papers within the time frame designated by the ALJ.

(f) The ALJ cannot draw any adverse inferences if CMS or a contractor decides not to participate in any proceedings before an ALJ, including the hearing.

§ 405.1012 When CMS or its contractors may be a party to a hearing.

(a) CMS and/or one or more of its contractors, including a QIC, may be a party to an ALJ hearing unless the request for hearing is filed by an unrepresented beneficiary.

(b) CMS and/or the contractor(s) advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 days after receiving the notice of hearing.

(c) When CMS or one or more of its contractors participate in a hearing as a party, it may file position papers, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties. CMS or its contractor(s) will submit any position papers within the time frame specified by the ALJ. CMS or its contractor(s), when acting as parties, may also submit additional evidence to the ALJ within the time frame designated by the ALJ.

(d) The ALJ may not require CMS or a contractor to enter a case as a party or draw any adverse inferences if CMS or a contractor decides not to enter as a party.

§ 405.1014 Request for an ALJ hearing.

(a) *Content of the request.* The request for an ALJ hearing must be made in writing. The request must include all of the following—

(1) The name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed.

(2) The name and address of the appellant, when the appellant is not the beneficiary.

(3) The name and address of the designated representatives if any.

(4) The document control number assigned to the appeal by the QIC, if any.

(5) The dates of service.

(6) The reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed.

(7) A statement of any additional evidence to be submitted and the date it will be submitted.

(b) *When and where to file.* The request for an ALJ hearing after a QIC reconsideration must be filed—

(1) Within 60 days from the date the party receives notice of the QIC's reconsideration;

(2) With the entity specified in the QIC's reconsideration. The appellant must also send a copy of the request for hearing to the other parties. Failure to do so will toll the ALJ's 90-day adjudication deadline until all parties to the QIC reconsideration receive notice of the requested ALJ hearing. If the request for hearing is timely filed with an entity other than the entity specified in the QIC's reconsideration, the deadline specified in § 405.1016 for deciding the appeal begins on the date the entity specified in the QIC's reconsideration receives the request for hearing. If the request for hearing is filed with an entity, other than the entity specified in the QIC's reconsideration, the ALJ hearing office must notify the appellant of the date of receipt of the request and the commencement of the 90-day adjudication time frame.

(c) *Extension of time to request a hearing.* (1) If the request for hearing is not filed within 60 calendar days of receipt of the QIC's reconsideration, an appellant may request an extension for good cause (*See* §§ 405.942(b)(2) and 405.942(b)(3)).

(2) Any request for an extension of time must be in writing, give the reasons why the request for a hearing was not filed within the stated time period, and must be filed with the entity specified in the notice of reconsideration.

(3) If the ALJ finds there is good cause for missing the deadline, the time period for filing the hearing request will be extended. To determine whether good cause for late filing exists, the ALJ uses the standards set forth in § 405.942(b)(2) and § 405.942(b)(3).

(4) If a request for hearing is not timely filed, the adjudication period in § 405.1016 begins the date the ALJ

grants the request to extend the filing deadline.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§ 405.1016 Time frames for deciding an appeal before an ALJ.

(a) When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, the ALJ must issue a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90-day period beginning on the date the request for hearing is received by the entity specified in the QIC's notice of reconsideration, unless the 90-day period has been extended as provided in this subpart.

(b) The adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the entity specified in the QIC's reconsideration, or, if it is not timely filed, the date that the ALJ grants any extension to the filing deadline.

(c) When an appeal is escalated to the ALJ level because the QIC has not issued a reconsideration determination within the period specified in § 405.970, the ALJ must issue a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 180-day period beginning on the date that the request for escalation is received by the ALJ hearing office, unless the 180-day period is extended as provided in this subpart.

(d) When CMS or its contractor is a party to an ALJ hearing and a party requests discovery under § 405.1037 against another party to the hearing, the adjudication periods discussed in paragraphs (a) and (c) of this section are tolled.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005]

§ 405.1018 Submitting evidence before the ALJ hearing.

(a) Except as provided in this section, parties must submit all written evidence they wish to have considered at the hearing with the request for hearing (or within 10 days of receiving the notice of hearing).

(b) If a party submits written evidence later than 10 days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received is not counted toward the adjudication deadline specified in § 405.1016.

(c) Any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is not submitted prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker (see § 405.1028).

(d) The requirements of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1020 Time and place for a hearing before an ALJ.

(a) *General*. The ALJ sets the time and place for the hearing, and may change the time and place, if necessary.

(b) *Determining how appearances are made*. The ALJ will direct that the appearance of an individual be conducted by videoteleconferencing (VTC) if the ALJ finds that VTC technology is available to conduct the appearance. The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for one or more of the parties. The ALJ, with the concurrence of the Managing Field Office ALJ, may determine that an in-person hearing should be conducted if—

(1) VTC technology is not available; or

(2) Special or extraordinary circumstances exist.

(c) *Notice of hearing*. (1) The ALJ sends a notice of hearing to all parties that filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination, the contractor that issued the initial determination, and the QIC that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require all parties to the ALJ hearing (and any

potential participant from CMS or its contractor who wishes to attend the hearing) to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing; or

(ii) Objecting to the proposed time and/or place of the hearing.

(d) *A party's right to waive a hearing.* A party may also waive the right to a hearing and request that the ALJ issue a decision based on the written evidence in the record. As provided in §405.1000, the ALJ may require the parties to attend a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may still hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In those cases, the ALJ will give the parties the opportunity to appear when the testimony is given but may hold the hearing even if none of the parties decide to appear.

(e) *A party's objection to time and place of hearing.* (1) If a party objects to the time and place of the hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing.

(2) The party must state the reason for the objection and state the time and place he or she wants the hearing to be held.

(3) The request must be in writing.

(4) The ALJ may change the time or place of the hearing if the party has good cause. (Section 405.1052(a)(2) provides the procedures the ALJ follows when a party does not respond to a notice of hearing and fails to appear at the time and place of the hearing.)

(f) *Good cause for changing the time or place.* The ALJ can find good cause for changing the time or place of the scheduled hearing and reschedule the hearing if the information available to the ALJ supports the party's contention that—

(1) The party or his or her representative is unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing; or

(3) Good cause exists as set forth in paragraph (g) of this section.

(g) *Good cause in other circumstances.* (1) In determining whether good cause exists in circumstances other than those set forth in paragraph (f) of this section, the ALJ considers the party's reason for requesting the change, the facts supporting the request, and the impact of the proposed change on the efficient administration of the hearing process.

(2) Factors evaluated to determine the impact of the change include, but are not limited to, the effect on processing other scheduled hearings, potential delays in rescheduling the hearing, and whether any prior changes were granted the party.

(3) Examples of other circumstances a party might give for requesting a change in the time or place of the hearing include, but are not limited to, the following:

(i) The party has attempted to obtain a representative but needs additional time.

(ii) The party's representative was appointed within 10 days of the scheduled hearing and needs additional time to prepare for the hearing.

(iii) The party's representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing.

(iv) A witness who will testify to facts material to a party's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained.

(v) Transportation is not readily available for a party to travel to the hearing.

(vi) The party is unrepresented, and is unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) that he or she has.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the appellant for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the

adjudication deadline specified in § 405.1016.

(i) *A party's request for an in-person hearing.* (1) If a party objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request an in-person hearing.

(2) The party must state the reason for the objection and state the time or place he or she wants the hearing to be held.

(3) The request must be in writing.

(4) When a party's request for an in-person hearing is granted, the party is deemed to have waived the 90-day time frame specified in § 405.1016.

(5) The ALJ may grant the request, with the concurrence of the Managing Field Office ALJ, upon a finding of good cause and will reschedule the hearing for a time and place when the party may appear in person before the ALJ.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed to the parties and other potential participants, as provided in § 405.1020(c) at their last known addresses, or given by personal service, unless the parties have indicated in writing that they do not wish to receive this notice. The notice is mailed or served at least 20 days before the hearing.

(b) *Notice information.* (1) The notice of hearing contains a statement of the specific issues to be decided and will inform the parties that they may designate a person to represent them during the proceedings.

(2) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that, if the appellant fails to appear at the scheduled hearing without good cause, the ALJ may dismiss the hearing request, and other information about the scheduling and conduct of the hearing.

(3) The appellant will also be told if his or her appearance or that of any other party or witness is scheduled by VTC, telephone, or in person. If the ALJ has scheduled the appellant or other party to appear at the hearing by VTC, the notice of hearing will advise that the scheduled place for the hearing is a VTC site and explain what it means to appear at the hearing by VTC.

(4) The notice advises the appellant or other parties that if they object to appearing by VTC or telephone, and wish instead to have their hearing at a time and place where they may appear in person before the ALJ, they must follow the procedures set forth at § 405.1020(i) for notifying the ALJ of their objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the appellant, any other party to the reconsideration, or their representative does not acknowledge receipt of the notice of hearing, the ALJ hearing office attempts to contact the party for an explanation.

(2) If the party states that he or she did not receive the notice of hearing, an amended notice is sent to him or her by certified mail or e-mail, if available. (See § 405.1052 for the procedures the ALJ follows in deciding if the time or place of a scheduled hearing will be changed if a party does not respond to the notice of hearing).

§ 405.1024 Objections to the issues.

(a) If a party objects to the issues described in the notice of hearing, he or she must notify the ALJ in writing at the earliest possible opportunity before the time set for the hearing, and no later than 5 days before the hearing.

(b) The party must state the reasons for his or her objections and send a copy of the objections to all other parties to the appeal.

(c) The ALJ makes a decision on the objections either in writing or at the hearing.

§ 405.1026 Disqualification of the ALJ.

(a) An ALJ cannot conduct a hearing if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) If a party objects to the ALJ who will conduct the hearing, the party must notify the ALJ within 10 calendar

days of the date of the notice of hearing. The ALJ considers the party's objections and decides whether to proceed with the hearing or withdraw.

(c) If the ALJ withdraws, another ALJ will be appointed to conduct the hearing. If the ALJ does not withdraw, the party may, after the ALJ has issued an action in the case, present his or her objections to the MAC in accordance with § 405.1100 *et seq*. The MAC will then consider whether the hearing decision should be revised or a new hearing held before another ALJ. If the case is escalated to the MAC after a hearing is held but before the ALJ issues a decision, the MAC considers the reasons the party objected to the ALJ during its review of the case and, if the MAC deems it necessary, may remand the case to another ALJ for a hearing and decision.

§ 405.1028 Prehearing case review of evidence submitted to the ALJ.

(a) *Examination of any new evidence*. After a hearing is requested but before it is held, the ALJ will examine any new evidence submitted with the request for hearing (or within 10 days of receiving the notice of hearing) as specified in § 405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether the provider, supplier, or beneficiary represented by a provider or supplier had good cause for submitting the evidence for the first time at the ALJ level.

(b) *Determining if good cause exists*. An ALJ finds good cause, for example, when the new evidence is material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration.

(c) *If good cause does not exist*. If the ALJ determines that there was not good cause for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(d) *Notification to all parties*. As soon as possible, but no later than the start of the hearing, the ALJ must notify all parties that the evidence is excluded from the hearing.

§ 405.1030 ALJ hearing procedures.

(a) *General rule*. A hearing is open to the parties and to other persons the ALJ considers necessary and proper.

(b) *At the hearing*. At the hearing, the ALJ fully examines the issues, questions the parties and other witnesses, and may accept documents that are material to the issues consistent with § 405.1018 and § 405.1028.

(c) *Missing evidence*. The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing. If the missing evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine if the appellant had good cause for not producing the evidence earlier.

(d) *Good cause exists*. If good cause exists, the ALJ considers the evidence in deciding the case and the adjudication period specified in § 405.1016 is tolled from the date of the hearing to the date the evidence is submitted.

(e) *Good cause does not exist*. If the ALJ determines that there was not good cause for not submitting the evidence sooner, the evidence is excluded.

(f) *Reopen the hearing*. The ALJ may also reopen the hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence pursuant to § 405.986. The ALJ may decide when the evidence is presented and when the issues are discussed.

§ 405.1032 Issues before an ALJ.

(a) *General rule*. The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term ''party'' does not include a representative of CMS or one of its contractors that may be participating in the hearing.) However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and may consider it an issue at the hearing.

(b) *New issues*—(1) *General*. The ALJ may consider a new issue at the hearing if he or she notifies all of the parties about the new issue any time before the start of the hearing. The new issue may include issues resulting from the participation of CMS at the ALJ level of adjudication and from any evidence and position papers submitted by CMS for the first time to the ALJ. The ALJ or any party may raise a new issue; however, the ALJ may only consider a new issue if its resolution—

(i) Could have a material impact on the claim or claims that are the subject of the request for hearing; and

(ii) Is permissible under the rules governing reopening of determinations and decisions (see § 405.980).

(2) [Reserved]

(c) *Adding claims to a pending appeal*. An ALJ cannot add any claim, including one that is related to an issue that is appropriately before an ALJ, to a pending appeal unless it has been adjudicated at the lower appeals levels and all parties are notified of the new issue(s) before the start of the hearing.

§ 405.1034 When an ALJ may remand a case to the QIC.

(a) *General*. If an ALJ believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, then the ALJ may either:

(1) Remand the case to the QIC that issued the reconsideration or

(2) Retain jurisdiction of the case and request that the contractor forward the missing information to the appropriate hearing office.

(b) *ALJ remands a case to a QIC*. Consistent with § 405.1004 (b), the ALJ will remand a case to the appropriate QIC if the ALJ determines that a QIC's dismissal of a request for reconsideration was in error.

(c) *Relationship to local and national coverage determination appeals process*. (1) The ALJ remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to 42 CFR 426.460(b)(1), 426.488(b), or 426.560(b)(1).

(2) Unless the appellant is entitled to relief pursuant to 42 CFR 426.460(b)(1), 426.488(b), or 426.560(b)(1), the ALJ applies the LCD or NCD in place on the date the item or service was provided.

§ 405.1036 Description of an ALJ hearing process.

(a) *The right to appear and present evidence*. (1) Any party to a hearing has the right to appear before the ALJ to present evidence and to state his or her position. A party may appear by video-teleconferencing (VTC), telephone, or in person as determined under § 405.1020.

(2) A party may also make his or her appearance by means of a representative, who may make the appearance by VTC, telephone, or in person, as determined under § 405.1020.

(3) Witness testimony may be given and CMS participation may also be accomplished by VTC, telephone, or in person, as determined under § 405.1020.

(b) *Waiver of the right to appear*. (1) A party may send the ALJ a written statement indicating that he or she does not wish to appear at the hearing.

(2) The appellant may subsequently withdraw his or her waiver at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the appellant agrees to an extension of the adjudication period as specified in § 405.1016 that may be necessary to schedule and hold the hearing.

(3) Other parties may withdraw their waiver up to the date of the scheduled hearing, if any. Even if all of the parties waive their right to appear at a hearing, the ALJ may require them to attend an oral hearing if he or she believes that a personal appearance and testimony by the appellant or any other party is necessary to decide the case.

(c) *Presenting written statements and oral arguments*. A party or a person designated to act as a party's representative may appear before the ALJ to state the party's case, to present a written summary of the case, or to enter written statements about the facts and law material to the case in the record. A copy of any written statements must be provided to the other parties to a hearing, if any, at the same time they are submitted to the ALJ.

(d) *Waiver of adjudication period.* At any time during the hearing process, the appellant may waive the adjudication deadline specified in §405.1016 for issuing a hearing decision. The waiver may be for a specific period of time agreed upon by the ALJ and the appellant.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence is not admissible in court under the rules of evidence used by the court.

(f) *Subpoenas.* (1) When it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative or at the request of a party, issue subpoenas for the appearance and testimony of witnesses and for a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying.

(2) A party's written request for a subpoena must—

(i) Give the names of the witnesses or documents to be produced;

(ii) Describe the address or location of the witnesses or documents with sufficient detail to find them;

(iii) State the important facts that the witness or document is expected to prove; and

(iv) Indicate why these facts cannot be proven without issuing a subpoena.

(3) Parties to a hearing who wish to subpoena documents or witnesses must file a written request for the issuance of a subpoena with the requirements set out in paragraph (f)(2) of this section with the ALJ within 10 calendar days of receipt of the notice of hearing.

(4) Where a party has requested a subpoena, a subpoena will be issued only where a party—

(i) Has sought discovery;

(ii) Has filed a motion to compel;

(iii) Has had that motion granted by the ALJ; and

(iv) Nevertheless, has not received the requested discovery.

(5) Reviewability of subpoena rulings—

(i) *General rule.* An ALJ ruling on a subpoena request is not subject to immediate review by the MAC. The ruling may be reviewed solely during the course of the MAC's review specified in §405.1102, §405.1104, or §405.1110, as applicable. *Exception.* To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before an ALJ, the MAC may review immediately the subpoena or that portion of the subpoena as applicable.

(ii) Where CMS objects to a discovery ruling, the MAC must take review and the discovery ruling at issue is automatically stayed pending the MAC's order.

(iii) Upon notice to the ALJ that a party or non-party, as applicable, intends to seek MAC review of the subpoena, the ALJ must stay all proceedings affected by the subpoena.

(iv) The ALJ determines the length of the stay under the circumstances of a given case, but in no event is the stay less than 15 days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek MAC review.

(v) If the MAC grants a request for review of the subpoena, the subpoena or portion of the subpoena, as applicable, is stayed until the MAC issues a written decision that affirms, reverses, or modifies the ALJ's action on the subpoena.

(vi) If the MAC does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ALJ's action stands.

(6) Enforcement. (i) If the ALJ determines, whether on his or her own motion or at the request of a party, that a party or non-party subject to a subpoena issued under this section has refused to comply with the subpoena, the ALJ may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(ii) Any enforcement request by an ALJ must consist of a written notice to the Secretary describing in detail the ALJ's findings of noncompliance and his or her specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the party or nonparty subject to the subpoena.

(iii) The ALJ must promptly mail a copy of the notice and related documents to the party subject to the subpoena, and to any other party and affected non-party to the appeal.

(g) *Witnesses at a hearing.* Witnesses may appear at a hearing. They testify under oath or affirmation, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation. The ALJ may ask the witnesses any questions relevant to the issues and allows the parties or their designated representatives to do so.

§ 405.1037 Discovery.

(a) *General rules.* (1) Discovery is permissible only when CMS or its contractor elects to participate in an ALJ hearing as a party.

(2) The ALJ may permit discovery of a matter that is relevant to the specific subject matter of the ALJ hearing, provided the matter is not privileged or otherwise protected from disclosure and the ALJ determines that the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate.

(3) Any discovery initiated by a party must comply with all requirements and limitations of this section, along with any further requirements or limitations ordered by the ALJ.

(b) *Limitations on discovery.* Any discovery before the ALJ is limited.

(1) A party may request of another party the reasonable production of documents for inspection and copying.

(2) A party may not take the deposition, upon oral or written examination, of another party unless the proposed deponent agrees to the deposition or the ALJ finds that the proposed deposition is necessary and appropriate in order to secure the deponent's testimony for an ALJ hearing.

(3) A party may not request admissions or send interrogatories or take any other form of discovery not permitted under this section.

(c) *Time limits.* (1) A party's discovery request is timely if the date of receipt of a request by another party is no later than the date specified by the ALJ.

(2) A party may not conduct discovery any later than the date specified by the ALJ.

(3) Before ruling on a request to extend the time for requesting discovery or for conducting discovery, the ALJ must give the other parties to the appeal a reasonable period to respond to the extension request.

(4) The ALJ may extend the time in which to request discovery or conduct discovery only if the requesting party establishes that it was not dilatory or otherwise at fault in not meeting the original discovery deadline.

(5) If the ALJ grants the extension request, it must impose a new discovery deadline and, if necessary, reschedule the hearing date so that all discoveries end no later than 45 days before the hearing.

(d) *Motions to compel or for protective order.* (1) Each party is required to make a good faith effort to resolve or narrow any discovery dispute.

(2) A party may submit to the ALJ a motion to compel discovery that is permitted under this section or any ALJ order, and a party may submit a motion for a protective order regarding any discovery request to the ALJ.

(3) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute. The declaration must also be included with any response to a motion to compel or for protective order.

(4) The ALJ must decide any motion in accordance with this section and any prior discovery ruling in the appeal.

(5) The ALJ must issue and mail to each party a discovery ruling that grants or denies the motion to compel or for protective order in whole or in part; if applicable, the discovery ruling must specifically identify any part of the disputed discovery request upheld and any part rejected, and impose any limits on discovery the ALJ finds necessary and appropriate.

(e) *Reviewability of discovery and disclosure rulings—*

(1) *General rule.* An ALJ discovery ruling, or an ALJ disclosure ruling such as one issued at a hearing is not subject to immediate review by the MAC. The ruling may be reviewed solely during the course of the MAC's review specified in § 405.1100, § 405.1102, § 405.1104, or § 405.1110, as applicable.

(2) *Exception*. To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the ALJ, the MAC may review that portion of the discovery or disclosure ruling immediately.

(i) Where CMS objects to a discovery ruling, the MAC must take review and the discovery ruling at issue is automatically stayed pending the MAC's order.

(ii) Upon notice to the ALJ that a party intends to seek MAC review of the ruling, the ALJ must stay all proceedings affected by the ruling.

(iii) The ALJ determines the length of the stay under the circumstances of a given case, but in no event must the length of the stay be less than 15 days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek MAC review.

(iv) Where CMS requests the MAC to take review of a discovery ruling or where the MAC grants a request, made by a party other than CMS, to review a discovery ruling, the ruling is stayed until the time the MAC issues a written decision that affirms, reverses, modifies, or remands the ALJ's ruling.

(v) With respect to a request from a party, other than CMS, for review of a discovery ruling, if the MAC does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ruling stands.

(f) *Adjudication time frames*. If a party requests discovery from another party to the ALJ hearing, the ALJ adjudication time frame specified in § 405.1016 is tolled until the discovery dispute is resolved.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1038 Deciding a case without a hearing before an ALJ.

(a) *Decision wholly favorable*. If the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, the ALJ may issue a hearing decision without giving the parties prior notice and without holding a hearing. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Parties do not wish to appear*. (1) The ALJ may decide a case on the record and not conduct a hearing if—

(i) All the parties indicate in writing that they do not wish to appear before the ALJ at a hearing, including a hearing conducted by telephone or videoconferencing, if available; or

(ii) The appellant lives outside the United States and does not inform the ALJ that he or she wants to appear, and there are no other parties who wish to appear.

(2) When a hearing is not held, the decision of the ALJ must refer to the evidence in the record on which the decision was based.

§ 405.1040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of any party to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) The ALJ informs the parties of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless a party indicates in writing that it does not wish to receive a written notice of the conference.

(c) At the conference, the ALJ may consider matters in addition to those stated in the notice of hearing, if the parties consent in writing. A record of the conference is made.

(d) The ALJ issues an order stating all agreements and actions resulting from the conference. If the parties do not object, the agreements and actions become part of the hearing record and are binding on all parties.

§ 405.1042 The administrative record.

(a) *Creating the record*. (1) The ALJ makes a complete record of the evidence, including the hearing proceedings, if any.

(2) The record will include marked as exhibits, the documents used in making the decision under review, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ admits. In the

record, the ALJ must also discuss any evidence excluded under § 405.1028 and include a justification for excluding the evidence.

(3) A party may review the record at the hearing, or, if a hearing is not held, at any time before the ALJ's notice of decision is issued.

(4) If a request for review is filed or the case is escalated to the MAC, the complete record, including any recording of the hearing, is forwarded to the MAC.

(5) A typed transcription of the hearing is prepared if a party seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.*

(1) A party may request and receive a copy of all or part of the record, including the exhibits list, documentary evidence, and a copy of the tape of the oral proceedings. The party may be asked to pay the costs of providing these items.

(2) If a party requests all or part of the record from the ALJ and an opportunity to comment on the record, the time beginning with the ALJ's receipt of the request through the expiration of the time granted for the party's response does not count toward the 90-day adjudication deadline.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1044 Consolidated hearing before an ALJ.

(a) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing or hearings pending before the same ALJ.

(b) It is within the discretion of the ALJ to grant or deny an appellant's request for consolidation. In considering an appellant's request, the ALJ may consider factors such as whether the claims at issue may be more efficiently decided if the requests for hearing are combined. In considering the appellant's request for consolidation, the ALJ must take into account the adjudication deadlines for each case and may require an appellant to waive the adjudication deadline associated with one or more cases if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(c) The ALJ may also propose on his or her own motion to consolidate two or more cases in one hearing for administrative efficiency, but may not require an appellant to waive the adjudication deadline for any of the consolidated cases.

(d) Before consolidating a hearing, the ALJ must notify CMS of his or her intention to do so, and CMS may then elect to participate in the consolidated hearing, as a party, by sending written notice to the ALJ within 10 days after receipt of the ALJ's notice of the consolidation.

(e) If the ALJ decides to hold a consolidated hearing, he or she may make either a consolidated decision and record or a separate decision and record on each claim. The ALJ ensures that any evidence that is common to all claims and material to the common issue to be decided is included in the consolidated record or each individual record, as applicable.

§ 405.1046 Notice of an ALJ decision.

(a) *General rule.* Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record. The ALJ mails a copy of the decision to all the parties at their last known address, to the QIC that issued the reconsideration determination, and to the contractor that issued the initial determination. For overpayment cases involving multiple beneficiaries, where there is no beneficiary liability, the ALJ may choose to send written notice only to the appellant. In the event a payment will be made to a provider or supplier in conjunction with this ALJ decision, the contractor must also issue a revised electronic or paper remittance advice to that provider or supplier.

(b) *Content of the notice.* The decision must be written in a manner calculated

to be understood by a beneficiary and must include—

(1) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(2) The procedures for obtaining additional information concerning the decision; and

(3) Notification of the right to appeal the decision to the MAC, including instructions on how to initiate an appeal under this section.

(c) *Limitation on decision.* When the amount of payment for an item or service is an issue before the ALJ, the ALJ may make a finding as to the amount of payment due. If the ALJ makes a finding concerning payment when the amount of payment was not an issue before the ALJ, the contractor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's decision is not final for purposes of determining the amount of payment due. The amount of payment determined by the contractor in effectuating the ALJ's decision is a new initial determination under § 405.924.

(d) *Timing of decision.* The ALJ issues a decision by the end of the 90-day period beginning on the date when the request for hearing is received by the entity specified in the QIC's reconsideration, unless the 90-day period is extended as provided in § 405.1016.

(e) *Recommended decision.* An ALJ issues a recommended decision if he or she is directed to do so in the MAC's remand order. An ALJ may not issue a recommended decision on his or her own motion. The ALJ mails a copy of the recommended decision to all the parties at their last known address.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1048 The effect of an ALJ's decision.

The decision of the ALJ is binding on all parties to the hearing unless—

(a) A party to the hearing requests a review of the decision by the MAC within the stated time period or the MAC reviews the decision issued by an ALJ under the procedures set forth in § 405.1110, and the MAC either issues a final action or the appeal is escalated to Federal district court under the provisions at § 405.1132 and the Federal district court issues a decision.

(b) The decision is reopened and revised by an ALJ or the MAC under the procedures explained in § 405.980;

(c) The expedited access to judicial review process at § 405.990 is used;

(d) The ALJ's decision is a recommended decision directed to the MAC and the MAC issues a decision; or

(e) In a case remanded by a Federal district court, the MAC assumes jurisdiction under the procedures in § 405.1138 and the MAC issues a decision.

§ 405.1050 Removal of a hearing request from an ALJ to the MAC.

If a request for hearing is pending before an ALJ, the MAC may assume responsibility for holding a hearing by requesting that the ALJ send the hearing request to it. If the MAC holds a hearing, it conducts the hearing according to the rules for hearings before an ALJ. Notice is mailed to all parties at their last known address informing them that the MAC has assumed responsibility for the case.

§ 405.1052 Dismissal of a request for a hearing before an ALJ.

Dismissal of a request for a hearing is in accordance with the following:

(a) An ALJ dismisses a request for a hearing under any of the following conditions:

(1) At any time before notice of the hearing decision is mailed, if only one party requested the hearing and that party asks to withdraw the request. This request may be submitted in writing to the ALJ or made orally at the hearing. The request for withdrawal must include a clear statement that the appellant is withdrawing the request for hearing and does not intend to further proceed with the appeal. If an attorney, or other legal professional on behalf of a beneficiary or other appellant files the request for withdrawal, the ALJ may presume that the representative has advised the appellant of the consequences of the withdrawal and dismissal.

(2) Neither the party that requested the hearing nor the party's representative appears at the time and place set for the hearing, if—

(i) The party was notified before the time set for the hearing that the request for hearing might be dismissed without further notice for failure to appear;

(ii) The party did not appear at the time and place of hearing and does not contact the ALJ hearing office within 10 days and provide good cause for not appearing; or

(iii) The ALJ sends a notice to the party asking why the party did not appear; and the party does not respond to the ALJ's notice within 10 days or does not provide good cause for the failure to appear.

(iv) In determining whether good cause exists under this paragraph (a)(2), the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language), that the party may have.

(3) The person or entity requesting a hearing has no right to it under § 405.1002.

(4) The party did not request a hearing within the stated time period and the ALJ has not found good cause for extending the deadline, as provided in § 405.1014(c).

(5) The beneficiary whose claim is being appealed died while the request for hearing is pending and all of the following criteria apply:

(i) The request for hearing was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1002.

(iii) No other individual or entity filed a valid and timely request for an ALJ hearing in accordance to § 405.1014.

(6) The ALJ dismisses a hearing request entirely or refuses to consider any one or more of the issues because a QIC, an ALJ or the MAC has made a previous determination or decision under this subpart about the appellant's rights on the same facts and on the same issue(s) or claim(s), and this previous determination or decision has become final by either administrative or judicial action.

(7) The appellant abandons the request for hearing. An ALJ may conclude that an appellant has abandoned a request for hearing when the ALJ hearing office attempts to schedule a hearing and is unable to contact the appellant after making reasonable efforts to do so.

(b) *Notice of dismissal.* The ALJ mails a written notice of the dismissal of the hearing request to all parties at their last known address. The notice states that there is a right to request that the MAC vacate the dismissal action.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1054 Effect of dismissal of a request for a hearing before an ALJ.

The dismissal of a request for a hearing is binding, unless it is vacated by the MAC under § 405.1108(b).

APPLICABILITY OF MEDICARE COVERAGE POLICIES

§ 405.1060 Applicability of national coverage determinations (NCDs).

(a) *General rule.* (1) An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under Medicare or a determination of the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act as well as under other applicable provisions of the Act.

(4) An NCD is binding on fiscal intermediaries, carriers, QIOs, QICs, ALJs, and the MAC.

(b) *Review by an ALJ.* (1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

(c) *Review by the MAC.* (1) The MAC may not disregard, set aside, or otherwise review an NCD for purposes of a section 1869 claim appeal, except that the DAB may review NCDs as provided under part 426 of this title.

(2) The MAC may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ and MAC.

(a) ALJs and the MAC are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or MAC declines to follow a policy in a particular case, the ALJ or MAC decision must explain the reasons why the policy was not followed. An ALJ or MAC decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

(c) An ALJ or MAC may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

§ 405.1063 Applicability of CMS Rulings.

CMS Rulings are published under the authority of the Administrator, CMS. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

§ 405.1064 ALJ decisions involving statistical samples.

When an appeal from the QIC involves an overpayment issue and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of the entire statistical sample used by the QIC.

MEDICARE APPEALS COUNCIL REVIEW

§ 405.1100 Medicare Appeals Council review: General.

(a) The appellant or any other party to the hearing may request that the MAC review an ALJ's decision or dismissal.

(b) Under circumstances set forth in § 405.1104 and 405.1108, the appellant may request that a case be escalated to the MAC for a decision even if the ALJ has not issued a decision or dismissal in his or her case.

(c) When the MAC reviews an ALJ's decision, it undertakes a de novo review. The MAC issues a final action or remands a case to the ALJ within 90 days of receipt of the appellant's request for review, unless the 90-day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the ALJ level to the MAC, the MAC will issue a final action or remand the case to the ALJ within 180 days of receipt of the appellant's request for escalation, unless the 180-day period is extended as provided in this subpart.

§ 405.1102 Request for MAC review when ALJ issues decision or dismissal.

(a)(1) A party to the ALJ hearing may request a MAC review if the party files a written request for a MAC review within 60 days after receipt of the ALJ's decision or dismissal.

(2) For purposes of this section, the date of receipt of the ALJ's decision or dismissal is presumed to be 5 days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(3) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's action.

(b) A party requesting a review may ask that the time for filing a request for MAC review be extended if—

(1) The request for an extension of time is in writing;

(2) It is filed with the MAC; and

(3) It explains why the request for review was not filed within the stated time period. If the MAC finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards outlined at § 405.942(b)(2) and § 405.942(b)(3).

(c) A party does not have the right to seek MAC review of an ALJ's remand to a QIC or an ALJ's affirmation of a QIC's dismissal of a request for reconsideration.

(d) For purposes of requesting MAC review (§ 405.1100 through § 405.1140), unless specifically excepted the term, ''party,'' includes CMS where CMS has entered into a case as a party according to § 405.1012. The term, ''appellant,'' does not include CMS, where CMS has entered into a case as a party according to § 405.1012.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1104 Request for MAC review when an ALJ does not issue a decision timely.

(a) *Requesting escalation.* An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending before the ALJ at the end of the applicable ALJ adjudication period under § 405.1016 may request MAC review if—

(1) The appellant files a written request with the ALJ to escalate the appeal to the MAC after the adjudication period has expired; and

(2) The ALJ does not issue a final action or remand the case to the QIC within the later of 5 days of receiving the request for escalation or 5 days from the end of the applicable adjudication period set forth in § 405.1016.

(b) *Escalation.* (1) If the ALJ is not able to issue a final action or remand within the time period set forth in paragraph (a)(2) of this section, he or she sends notice to the appellant.

(2) The notice acknowledges receipt of the request for escalation, and confirms that the ALJ is not able to issue a final action or remand order within the statutory time frame.

(3) If the ALJ does not act on a request for escalation within the time period set forth in paragraph (a)(2) of this section or does not send the required notice to the appellant, the QIC decision becomes a final administrative decision for purposes of MAC review.

(c) *No escalation.* If the ALJ's adjudication period set forth in § 405.1016 expires, the case remains with the ALJ until a final action is issued or the appellant requests escalation to the MAC.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1106 Where a request for review or escalation may be filed.

(a) When a request for a MAC review is filed after an ALJ has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's action. The appellant must also send a copy of the request for review to the other parties to the ALJ decision or dismissal. Failure to copy the other parties tolls the MAC's adjudication deadline set forth in § 405.1100 until all parties to the hearing receive notice of the request for MAC review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the MAC's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's action, the MAC sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication time frame.

(b) If an appellant files a request to escalate an appeal to the MAC level because the ALJ has not completed his or her action on the request for hearing within the adjudication deadline under § 405.1016, the request for escalation must be filed with both the ALJ and the MAC. The appellant must also send a copy of the request for escalation to the other parties. Failure to copy the other parties tolls the MAC's adjudication deadline set forth in § 405.1100 until

all parties to the hearing receive notice of the request for MAC review. In a case that has been escalated from the ALJ, the MAC's 180-day period to issue a final action or remand the case to the ALJ begins on the date the request for escalation is received by the MAC.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§405.1108 MAC actions when request for review or escalation is filed.

(a) Except as specified in paragraphs (c) and (d) of this section, when a party requests that the MAC review an ALJ's decision, the MAC will review the ALJ's decision *de novo*. The party requesting review does not have a right to a hearing before the MAC. The MAC will consider all of the evidence in the administrative record. Upon completion of its review, the MAC may adopt, modify, or reverse the ALJ's decision or remand the case to an ALJ for further proceedings.

(b) When a party requests that the MAC review an ALJ's dismissal, the MAC may deny review or vacate the dismissal and remand the case to the ALJ for further proceedings.

(c) The MAC will dismiss a request for review when the party requesting review does not have a right to a review by the MAC, or will dismiss the request for a hearing for any reason that the ALJ could have dismissed the request for hearing.

(d) When an appellant requests escalation of a case from the ALJ level to the MAC, the MAC may take any of the following actions:

(1) Issue a decision based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ before the case was escalated.

(2) Conduct any additional proceedings, including a hearing, that the MAC determines are necessary to issue a decision.

(3) Remand the case to an ALJ for further proceedings, including a hearing.

(4) Dismiss the request for MAC review because the appellant does not have the right to escalate the appeal.

(5) Dismiss the request for a hearing for any reason that the ALJ could have dismissed the request.

§405.1110 MAC reviews on its own motion.

(a) *General rule*. The MAC may decide on its own motion to review a decision or dismissal issued by an ALJ. CMS or any of its contractors may refer a case to the MAC for it to consider reviewing under this authority anytime within 60 days after the date of an ALJ's decision or dismissal.

(b) *Referral of cases*. (1) CMS or any of its contractors may refer a case to the MAC if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS may also request that the MAC take own motion review of a case if—

(i) CMS or its contractor participated in the appeal at the ALJ level; and

(ii) In CMS' view, the ALJ's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ abused his or her discretion.

(2) CMS's referral to the MAC is made in writing and must be filed with the MAC no later than 60 days after the ALJ's decision or dismissal is issued. The written referral will state the reasons why CMS believes that the MAC must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's action and to the ALJ. Parties to the ALJ's action may file exceptions to the referral by submitting written comments to the MAC within 20 days of the referral notice. A party submitting comments to the MAC must send such comments to CMS and all other parties to the ALJ's decision.

(c) *Standard of review*. (1) Referral by CMS after participation at the ALJ level. If CMS or its contractor participated in an appeal at the ALJ level, the MAC exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the MAC will limit its consideration of the

ALJ's action to those exceptions raised by CMS.

(2) *Referral by CMS when CMS did not participate in the ALJ proceedings or appear as a party*. The MAC will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS.

(d) *MAC's action*. If the MAC decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The MAC may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ for further proceedings or may dismiss a hearing request. The MAC must issue its action no later than 90 days after receipt of the CMS referral, unless the 90-day period has been extended as provided in this subpart. The MAC may not, however, issue its action before the 20-day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the MAC does not act within the applicable adjudication deadline, the ALJ's decision or dismissal remains the final action in the case.

§ 405.1112 Content of request for review.

(a) The request for MAC review must be filed with the MAC or appropriate ALJ hearing office. The request for review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare health insurance claim number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's final action, if any, if the party is requesting escalation from the ALJ to the MAC, the hearing office in which the appellant's request for hearing is pending; and the name and signature of the party or the representative of the party; and any other information CMS may decide.

(b) The request for review must identify the parts of the ALJ action with which the party requesting review disagrees and explain why he or she disagrees with the ALJ's decision, dismissal, or other determination being appealed. For example, if the party requesting review believes that the ALJ's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(c) The MAC will limit its review of an ALJ's actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. For purposes of this section only, we define a representative as anyone who has accepted an appointment as the beneficiary's representative, except a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005]

§ 405.1114 Dismissal of request for review.

The MAC dismisses a request for review if the party requesting review did not file the request within the stated period of time and the time for filing has not been extended. The MAC also dismisses the request for review if—

(a) The party asks to withdraw the request for review;

(b) The party does not have a right to request MAC review; or

(c) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(1) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the MAC considers whether the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for

subsequent similar services under the limitation of liability provisions based on the denial of the services at issue;

(2) No other individual or entity with a financial interest in the case wishes to pursue an appeal under §405.1102;

(3) No other party to the ALJ hearing filed a valid and timely review request under §405.1102 and §405.1112.

§405.1116 Effect of dismissal of request for MAC review or request for hearing.

The dismissal of a request for MAC review or denial of a request for review of a dismissal issued by an ALJ is binding and not subject to further review unless reopened and vacated by the MAC. The MAC's dismissal of a request for hearing is also binding and not subject to judicial review.

§405.1118 Obtaining evidence from the MAC.

A party may request and receive a copy of all or part of the record of the ALJ hearing, including the exhibits list, documentary evidence, and a copy of the tape of the oral proceedings. However, the party may be asked to pay the costs of providing these items. If a party requests evidence from the MAC and an opportunity to comment on that evidence, the time beginning with the MAC's receipt of the request for evidence through the expiration of the time granted for the party's response will not be counted toward the 90-day adjudication deadline.

§405.1120 Filing briefs with the MAC.

Upon request, the MAC will give the party requesting review, as well as all other parties, a reasonable opportunity to file briefs or other written statements about the facts and law relevant to the case. Any party who submits a brief or statement must send a copy to all of the other parties. Unless the party requesting review files the brief or other statement with the request for review, the time beginning with the date of receipt of the request to submit the brief and ending with the date the brief is received by the MAC will not be counted toward the adjudication timeframe set forth in §405.1100. The MAC may also request, but not require, CMS or its contractor to file a brief or position paper if the MAC determines that it is necessary to resolve the issues in the case. The MAC will not draw any adverse inference if CMS or a contractor either participates, or decides not to participate in MAC review.

§405.1122 What evidence may be submitted to the MAC.

(a) *Appeal before the MAC on request for review of ALJ's decision.* (1) If the MAC is reviewing an ALJ's decision, the MAC limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ. However, if the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level, the MAC considers any evidence related to that issue that is submitted with the request for review.

(2) If the MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the MAC may remand the case to an ALJ to obtain the evidence and issue a new decision.

(b) *Appeal before MAC as a result of appellant's request for escalation.* (1) If the MAC is reviewing a case that is escalated from the ALJ level to the MAC, the MAC will decide the case based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ before the case was escalated.

(2) If the MAC receives additional evidence with the request for escalation that is material to the question to be decided, or determines that additional evidence is needed to resolve the issues in the case, and the record provided to the MAC indicates that the previous decision-makers did not attempt to obtain the evidence before escalation, the MAC may remand the case to an ALJ to consider or obtain the evidence and issue a new decision.

(c) *Evidence related to issues previously considered by the QIC.* (1) If new evidence related to issues previously considered by the QIC is submitted to the MAC by a provider, supplier, or a beneficiary represented by a provider or supplier, the MAC must determine if

the provider, supplier, or the beneficiary represented by a provider or supplier had good cause for submitting it for the first time at the MAC level.

(2) If the MAC determines that good cause does not exist, the MAC must exclude the evidence from the proceeding, may not consider it in reaching a decision, and may not remand the issue to an ALJ.

(3) The MAC must notify all parties if it excludes the evidence. The MAC may remand to an ALJ if—

(i) The ALJ did not consider the new evidence submitted by the provider, supplier, or beneficiary represented by a provider or supplier because good cause did not exist; and

(ii) The MAC finds that good cause existed under § 405.1028 and the ALJ should have reviewed the evidence.

(iii) The new evidence is submitted by a party that is not a provider, supplier, or a beneficiary represented by a provider or supplier.

(d) *Subpoenas.* (1) When it is reasonably necessary for the full presentation of a case, the MAC may, on its own initiative or at the request of a party, issue subpoenas requiring a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying.

(2) A party's request for a subpoena must—

(i) Give a sufficient description of the documents to be produced;

(ii) State the important facts that the documents are expected to prove; and

(iii) Indicate why these facts could not be proven without issuing a subpoena.

(3) A party to the MAC review on escalation that wishes to subpoena documents must file a written request that complies with the requirements set out in paragraph (d)(2) of this section within 10 calendar days of the request for escalation.

(4) A subpoena will issue only where a party—

(i) Has sought discovery;

(ii) Has filed a motion to compel;

(iii) Has had that motion granted; and

(iv) Nevertheless, has still not received the requested discovery.

(e) Reviewability of subpoena rulings—

(1) *General rule.* A MAC ruling on a subpoena request is not subject to immediate review by the Secretary.

(2) Exception. (i) To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before the MAC, the Secretary may review immediately that subpoena or portion of the subpoena.

(ii) Upon notice to the MAC that a party or non-party, as applicable, intends to seek Secretary review of the subpoena, the MAC must stay all proceedings affected by the subpoena.

(iii) The MAC determines the length of the stay under the circumstances of a given case, but in no event is less than 15 days after the day on which the MAC received notice of the party or non-party's intent to seek Secretary review.

(iv) If the Secretary grants a request for review, the subpoena or portion of the subpoena, as applicable, is stayed until the Secretary issues a written decision that affirms, reverses, modifies, or remands the MAC's action for the subpoena.

(v) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifed and the MAC's action stands.

(f) *Enforcement.* (1) If the MAC determines, whether on its own motion or at the request of a party, that a party or non-party subject to a subpoena issued under this section has refused to comply with the subpoena, the MAC may request the Secretary to seek enforcement of the subpoena in accordance with section 205(c) of the Act, 42 U.S.C. 405(c).

(2) Any enforcement request by the MAC must consist of a written notice to the Secretary describing in detail the MAC's findings of noncompliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the party or nonparty subject to the subpoena.

(3) The MAC must promptly mail a copy of the notice and related documents to the party or non-party subject to the subpoena, and to any other party and affected non-party to the appeal.

(4) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the subpoena stands.

§405.1124 Oral argument.

A party may request to appear before the MAC to present oral argument.

(a) The MAC grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone.

(b) The MAC may decide on its own that oral argument is necessary to decide the issues in the case. If the MAC decides to hear oral argument, it tells the parties of the time and place of the oral argument at least 10 days before the scheduled date.

(c) In case of a previously unrepresented beneficiary, a newly hired representative may request an extension of time for preparation of the oral argument and the MAC must consider whether the extension is reasonable.

(d) The MAC may also request, but not require, CMS or its contractor to appear before it if the MAC determines that it may be helpful in resolving the issues in the case.

(e) The MAC will not draw any inference if CMS or a contractor decides not to participate in the oral argument.

§405.1126 Case remanded by the MAC.

(a) *When the MAC may remand a case.* Except as specified in §405.1122(c), the MAC may remand a case in which additional evidence is needed or additional action by the ALJ is required. The MAC will designate in its remand order whether the ALJ will issue a final decision or a recommended decision on remand.

(b) *Action by ALJ on remand.* The ALJ will take any action that is ordered by the MAC and may take any additional action that is not inconsistent with the MAC's remand order.

(c) *Notice when case is returned with a recommended decision.* When the ALJ sends a case to the MAC with a recommended decision, a notice is mailed to the parties at their last known address. The notice tells them that the case was sent to the MAC, explains the rules for filing briefs or other written statements with the MAC, and includes a copy of the recommended decision.

(d) *Filing briefs with the MAC when ALJ issues recommended decision.* (1) Any party to the recommended decision may file with the MAC briefs or other written statements about the facts and law relevant to the case within 20 days of the date on the recommended decision. Any party may ask the MAC for additional time to file briefs or statements. The MAC will extend this period, as appropriate, if the party shows that it has good cause for requesting the extension.

(2) All other rules for filing briefs with and obtaining evidence from the MAC follow the procedures explained in this subpart.

(e) *Procedures before the MAC.* (1) The MAC, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

(2) If the MAC determines that more evidence is required, it may again remand the case to an ALJ for further inquiry into the issues, rehearing, receipt of evidence, and another decision or recommended decision. However, if the MAC decides that it can get the additional evidence more quickly, it will take appropriate action.

§405.1128 Action of the MAC.

(a) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on MAC consideration of additional evidence in §405.1122, the MAC will make a decision or remand the case to an ALJ.

(b) The MAC may adopt, modify, or reverse the ALJ hearing decision or recommended decision.

(c) The MAC mails a copy of its decision to all the parties at their last known addresses. For overpayment cases involving multiple beneficiaries where there is no beneficiary liability the MAC may choose to send written notice only to the appellant. In the

event the decision will result in a payment to a provider or supplier, the Medicare contractor must issue any electronic or paper remittance advice notice to that provider or supplier.

§ 405.1130 Effect of the MAC's decision.

The MAC's decision is binding on all parties unless a Federal district court issues a decision modifying the MAC's decision or the decision is revised as the result of a reopening in accordance with § 405.980. A party may file an action in a Federal district court within 60 days after the date it receives notice of the MAC's decision.

§ 405.1132 Request for escalation to Federal court.

(a) If the MAC does not issue a decision or dismissal or remand the case to an ALJ within the adjudication period specified in § 405.1100, or as extended as provided in this subpart, the appellant may request that the appeal, other than an appeal of an ALJ dismissal, be escalated to Federal district court. Upon receipt of a request for escalation, the MAC may—

(1) Issue a decision or dismissal or remand the case to an ALJ, if that action is issued within the latter of 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period set forth in § 405.1100; or

(2) If the MAC is not able to issue a decision or dismissal or remand as set forth in paragraph (a)(1) of this section, it will send a notice to the appellant acknowledging receipt of the request for escalation and confirming that it is not able to issue a decision, dismissal or remand order within the statutory time frame.

(b) A party may file an action in a Federal district court within 60 days after the date it receives the MAC's notice that the MAC is not able to issue a final action or remand unless the party is appealing an ALJ dismissal.

§ 405.1134 Extension of time to file action in Federal district court.

(a) Any party to the MAC's decision or to a request for EAJR that has been certified by the review entity other than CMS may request that the time for filing an action in a Federal district court be extended.

(b) The request must—

(1) Be in writing.

(2) Give the reasons why the action was not filed within the stated time period.

(3) Be filed with the MAC.

(c) If the party shows that he or she had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards specified in § 405.942(b)(2) or (b)(3).

§ 405.1136 Judicial review.

(a) *General rules.* (1) To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a MAC decision, or an appellant who requests escalation to Federal district court if the MAC does not complete its review of the ALJ's decision within the applicable adjudication period, may obtain a court review if the amount remaining in controversy satisfies the requirements of § 405.1006(c).

(2) If the MAC's adjudication period set forth in § 405.1100 expires and the appellant does not request escalation to Federal district court, the case remains with the MAC until a final action is issued.

(b) *Court in which to file civil action.* (1) Any civil action described in paragraph (a) of this section must be filed in the district court of the United States for the judicial district in which the party resides or where such individual, institution, or agency has its principal place of business.

(2) If the party does not reside within any judicial district, or if the individual, institution, or agency does not have its principal place of business within any such judicial district, the civil action must be filed in the District Court of the United States for the District of Columbia.

(c) *Time for filing civil action.* (1) Any civil action described in paragraph (a) of this section must be filed within the time periods specified in § 405.1130, § 405.1132, or § 405.1134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the MAC's decision or the MAC's notice that it is not able to issue a decision within the statutory timeframe shall

be presumed to be 5 calendar days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in §405.990, the civil action must be filed within 60 days after receipt of the review entity's certification, except where the time is extended by the ALJ or MAC, as applicable, upon a showing of good cause.

(d) *Proper defendant.* (1) In any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant. Any civil action properly filed shall survive notwithstanding any change of the person holding the Office of the Secretary of HHS or any vacancy in such office.

(2) If the complaint is erroneously filed against the United States or against any agency, officer, or employee of the United States other than the Secretary, the plaintiff will be notified that he or she has named an incorrect defendant and is granted 60 days from the date of receipt of the notice in which to commence the action against the correct defendant, the Secretary.

(e) *Prohibition against judicial review of certain Part B regulations or instructions.* Under section 1869(e)(1) of the Act, a court may not review a regulation or instruction that relates to a method of payment under Medicare Part B if the regulation was published, or the instructions issued, before January 1, 1991.

(f) *Standard of review.* (1) Under section 205(g) of the Act, the findings of the Secretary of HHS as to any fact, if supported by substantial evidence, are conclusive.

(2) When the Secretary's decision is adverse to a party due to a party's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof a party must offer to establish entitlement to payment, the court will review only whether the proof conforms with the regulation and the validity of the regulation.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37705, June 30, 2005]

§405.1138 Case remanded by a Federal district court.

When a Federal district court remands a case to the Secretary for further consideration, unless the court order specifies otherwise, the MAC, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ with instructions to take action and either issue a decision, take other action, or return the case to the MAC with a recommended decision. If the MAC remands a case, the procedures specified in §405.1140 will be followed.

§405.1140 MAC review of ALJ decision in a case remanded by a Federal district court.

(a) *General rules.* (1) In accordance with §405.1138, when a case is remanded by a Federal district court for further consideration and the MAC remands the case to an ALJ, a decision subsequently issued by the ALJ becomes the final decision of the Secretary unless the MAC assumes jurisdiction.

(2) The MAC may assume jurisdiction based on written exceptions to the decision of the ALJ that a party files with the MAC or based on its authority under paragraph (c) of this section.

(3) The MAC either makes a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remands the case to an ALJ for further proceedings.

(b) *A party files exceptions disagreeing with the decision of the ALJ.* (1) If a party disagrees with an ALJ decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the MAC. Exceptions may be filed by submitting a written statement to the MAC setting forth the reasons for disagreeing with the decision of the ALJ. The party must file exceptions within 30 days of the date the party receives the decision of the ALJ or submit a written request for an extension within the 30-day period. The MAC will grant a timely request for a 30-day extension. A request for an extension of more than 30 days must include a statement of reasons as to why the party needs the additional time and may be granted if the MAC finds good cause under

the standard established in § 405.942(b)(2) or (b)(3).

(2) If written exceptions are timely filed, the MAC considers the party's reasons for disagreeing with the decision of the ALJ. If the MAC concludes that there is no reason to change the decision of the ALJ, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ is warranted. In this instance, the decision of the ALJ is the final decision of the Secretary after remand.

(3) When a party files written exceptions to the decision of the ALJ, the MAC may assume jurisdiction at any time. If the MAC assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or remanding the case to an ALJ for further proceedings, including a new decision. The new decision of the MAC is the final decision of the Secretary after remand.

(c) *MAC assumes jurisdiction without exceptions being filed.* (1) Any time within 60 days after the date of the decision of the ALJ, the MAC may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to all parties at their last known address.

(3) The parties will be provided with the opportunity to file briefs or other written statements with the MAC about the facts and law relevant to the case.

(4) After the briefs or other written statements are received or the time allowed (usually 30 days) for submitting them has expired, the MAC will either issue a final decision of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ for further proceedings, including a new decision.

(d) *Exceptions are not filed and the MAC does not otherwise assume jurisdiction.* If no exceptions are filed and the MAC does not assume jurisdiction of the cases within 60 days after the date of the ALJ's decision, the decision of the ALJ becomes the final decision of the Secretary after remand.

Subpart J—Expedited Determinations and Reconsiderations of Provider Service Terminations, and Procedures for Inpatient Hospital Discharges

SOURCE: 69 FR 69624, Nov. 26, 2004, unless otherwise noted.

§ 405.1200 Notifying beneficiaries of provider service terminations.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1200 through 405.1204, the term, provider, is defined as a home health agency (HHA), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), or hospice.

(2) For purposes of §§ 405.1200 through 405.1204, a termination of Medicare-covered service is a discharge of a beneficiary from a residential provider of services, or a complete cessation of coverage at the end of a course of treatment prescribed in a discrete increment, regardless of whether the beneficiary agrees that the services should end. A termination does not include a reduction in services. A termination also does not include the termination of one type of service by the provider if the beneficiary continues to receive other Medicare-covered services from the provider.

(b) *Advance written notice of service terminations.* Before any termination of services, the provider of the service must deliver valid written notice to the beneficiary of the provider's decision to terminate services. The provider must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* A provider must notify the beneficiary of the decision to terminate covered services no later than 2 days before the proposed end of the services. If the beneficiary's services are expected to be fewer than 2 days in duration, the provider must notify the beneficiary at the time of admission to the provider. If, in a nonresidential setting, the span of time between services exceeds 2 days, the notice must be given no later than the next to last time services are furnished.

(2) *Content of the notice.* The standardized termination notice must include the following information:

(i) The date that coverage of services ends;

(ii) The date that the beneficiary's financial liability for continued services begins;

(iii) A description of the beneficiary's right to an expedited determination under § 405.1202, including information about how to request an expedited determination and about a beneficiary's right to submit evidence showing that services must continue;

(iv) A beneficiary's right to receive the detailed information specified under § 405.1202(f); and

(v) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the termination notice is valid if—

(i) The beneficiary (or the beneficiary's authorized representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If a beneficiary refuses to sign the notice.* The provider may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(5) *Financial liability for failure to deliver valid notice.* A provider is financially liable for continued services until 2 days after the beneficiary receives valid notice as specified under paragraph (b)(3) of this section, or until the service termination date specified on the notice, whichever is later. A beneficiary may waive continuation of services if he or she agrees with being discharged sooner than the planned service termination date.

§ 405.1202 Expedited determination procedures.

(a) *Beneficiary's right to an expedited determination by the QIO.* A beneficiary has a right to an expedited determination by a QIO under the following circumstances:

(1) For services furnished by a nonresidential provider, the beneficiary disagrees with the provider of those services that services should be terminated, and a physician certifies that failure to continue the provision of the service(s) may place the beneficiary's health at significant risk.

(2) For services furnished by a residential provider or a hospice, the beneficiary disagrees with the provider's decision to discharge the beneficiary.

(b) *Requesting an expedited determination.* (1) A beneficiary who wishes to exercise the right to an expedited determination must submit a request for a determination to the QIO in the State in which the beneficiary is receiving those provider services, in writing or by telephone, by no later than noon of the calendar day following receipt of the provider's notice of termination. If the QIO is unable to accept the beneficiary's request, the beneficiary must submit the request by noon of the next day the QIO is available to accept a request.

(2) The beneficiary, or his or her representative, must be available to answer questions or to supply information that the QIO may request to conduct its review.

(3) The beneficiary may, but is not required to, submit evidence to be considered by a QIO in making its decision.

(4) If a beneficiary makes an untimely request for an expedited determination by a QIO, the QIO will accept the request and make a determination as soon as possible, but the 72-hour time frame under paragraph (e)(6) and the financial liability protection under paragraph (g) of this section do not apply.

(c) *Coverage of provider services.* Coverage of provider services continues until the date and time designated on the termination notice, unless the QIO reverses the provider's service termination decision. If the QIO's decision is delayed because the provider did not timely supply necessary information or records, the provider may be liable for the costs of any additional coverage, as determined by the QIO in accordance with paragraph (e)(7) of this section. If the QIO finds that the beneficiary did not receive valid notice, coverage of

provider services continues until at least 2 days after valid notice has been received. Continuation of coverage is not required if the QIO determines that coverage could pose a threat to the beneficiary's health or safety.

(d) *Burden of proof.* When a beneficiary requests an expedited determination by a QIO, the burden of proof rests with the provider to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) In order for the QIO to determine whether the provider has met the burden of proof, the provider should supply any and all information that a QIO requires to sustain the provider's termination decision, consistent with paragraph (f) of this section.

(2) The beneficiary may submit evidence to be considered by a QIO in making its decision.

(e) *Procedures the QIO must follow.* (1) On the day the QIO receives the request for an expedited determination under paragraph (b) of this section, it must immediately notify the provider of those services that a request for an expedited determination has been made.

(2) The QIO determines whether the provider delivered valid notice of the termination decision consistent with § 405.1200(b) and paragraph (f) of this section.

(3) The QIO examines the medical and other records that pertain to the services in dispute. If applicable, the QIO determines whether a physician has certified that failure to continue the provision of services may place the beneficiary's health at significant risk.

(4) The QIO must solicit the views of the beneficiary who requested the expedited determination.

(5) The QIO must provide an opportunity for the provider/practitioner to explain why the termination or discharge is appropriate.

(6) No later than 72 hours after receipt of the request for an expedited determination, the QIO must notify the beneficiary, beneficiary's physician, and the provider of services of its determination whether termination of Medicare coverage is the correct decision, either on the basis of medical necessity or based on other Medicare coverage policies.

(7) If the QIO does not receive the information needed to sustain a provider's decision to terminate services, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's provider services, the provider may be held financially liable for these services, as determined by the QIO.

(8) The QIO's initial notification may be by telephone, followed by a written notice including the following information:

(i) The rationale for the determination;

(ii) An explanation of the Medicare payment consequences of the determination and the date a beneficiary becomes fully liable for the services; and

(iii) Information about the beneficiary's right to a reconsideration of the QIO's determination, including how to request a reconsideration and the time period for doing so.

(f) *Responsibilities of providers.* (1) When a QIO notifies a provider that a beneficiary has requested an expedited determination, the provider must send a detailed notice to the beneficiary by close of business of the day of the QIO's notification. The detailed termination notice must include the following information:

(i) A specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered;

(ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including citations to the applicable Medicare policy rules or information about how the beneficiary may obtain a copy of the Medicare policy;

(iii) Facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case; and

(iv) Any other information required by CMS.

(2) Upon notification by the QIO of the request for an expedited determination, the provider must supply all information that the QIO needs to make its expedited determination, including a copy of the notices required under §405.1200(b) and under paragraph (f)(1) of this section. The provider must furnish this information as soon as possible, but no later than by close of business of the day the QIO notifies the provider of the request for an expedited determination. At the discretion of the QIO, the provider may make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(3) At a beneficiary's request, the provider must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO including records of any information provided by telephone. The provider may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The provider must accommodate such a request by no later than close of business of the first day after the material is requested.

(g) *Coverage during QIO review.* When a beneficiary requests an expedited determination in accordance with the procedures required by this section, the provider may not bill the beneficiary for any disputed services until the expedited determination process (and reconsideration process, if applicable) has been completed.

§405.1204 Expedited reconsiderations.

(a) *Beneficiary's right to an expedited reconsideration.* A beneficiary who is dissatisfied with a QIO's expedited determination may request an expedited reconsideration by the appropriate QIC.

(b) *Requesting an expedited reconsideration.* (1) A beneficiary who wishes to obtain an expedited reconsideration must submit a request for the reconsideration to the appropriate QIC, in writing or by telephone, by no later than noon of the calendar day following initial notification (whether by telephone or in writing) receipt of the QIO's determination. If the QIC is unable to accept the beneficiary's request, the beneficiary must submit the request by noon of the next day the QIC is available to accept a request.

(2) The beneficiary, or his or her representative, must be available to answer questions or supply information that the QIC may request to conduct its reconsideration.

(3) The beneficiary may, but is not required to, submit evidence to be considered by a QIC in making its decision.

(4) A beneficiary who does not file a timely request for an expedited QIC reconsideration subsequently may request a reconsideration under the standard claims appeal process, but the coverage protections described in paragraph (f) of this section would not extend through this reconsideration, nor would the timeframes or the escalation process described in paragraphs (c)(3) and (c)(5) of this section, respectively.

(c) *Procedures the QIC must follow.* (1) On the day the QIC receives the request for an expedited determination under paragraph (b) of this section, the QIC must immediately notify the QIO that made the expedited determination and the provider of services of the request for an expedited reconsideration.

(2) The QIC must offer the beneficiary and the provider an opportunity to provide further information.

(3) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, no later than 72 hours after receipt of the request for an expedited reconsideration, and any medical or other records needed for such reconsideration, the QIC must notify the QIO, the beneficiary, the beneficiary's physician, and the provider of services, of its decision on the reconsideration request.

(4) The QIC's initial notification may be done by telephone, followed by a written notice including:

(i) The rationale for the reconsideration decision;

(ii) An explanation of the Medicare payment consequences of the determination and the beneficiary's date of liability; and

(iii) Information about the beneficiary's right to appeal the QIC's reconsideration decision to an ALJ, including how to request an appeal and the time period for doing so.

(5) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, if the QIC does not issue a decision within 72 hours of receipt of the request, the QIC must notify the beneficiary of his or her right to have the case escalated to the ALJ hearing level if the amount remaining in controversy after the QIO determination is $100 or more.

(6) A beneficiary requesting an expedited reconsideration under this section may request (either in writing or orally) that the QIC grant such additional time as the beneficiary specifies (not to exceed 14 days) for the reconsideration. If an extension is granted, the deadlines in paragraph (c)(3) of this section do not apply.

(d) *Responsibilities of the QIO.* (1) When a QIC notifies a QIO that a beneficiary has requested an expedited reconsideration, the QIO must supply all information that the QIC needs to make its expedited reconsideration as soon as possible, but no later than by close of business of the day that the QIC notifies the QIO of the request for an expedited reconsideration.

(2) At a beneficiary's request, the QIO must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIC. The QIO may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The QIO must accommodate the request by no later than close of business of the first day after the material is requested.

(e) *Responsibilities of the provider.* A provider may, but is not required to, submit evidence to be considered by a QIC in making its decision. If a provider fails to comply with a QIC's request for additional information beyond that furnished to the QIO for purposes of the expedited determination, the QIC makes its reconsideration decision based on the information available.

(f) *Coverage during QIC reconsideration process.* When a beneficiary requests an expedited reconsideration in accordance with the deadline specified in (b)(1) of this section, the provider may not bill the beneficiary for any disputed services until the QIC makes its determination.

§ 405.1206 Expedited determinations for inpatient hospital discharges.

(a) *Beneficiary's right to an expedited determination for an inpatient hospital discharge.* A beneficiary who has received a notice of noncoverage under section 1154(e)(1) of the Act and 42 CFR 412.42(c)(3) may request an expedited determination by the QIO when a hospital (acting directly or through its utilization review committee), with physician concurrence, determines that inpatient care is no longer necessary. A beneficiary who timely requests an expedited QIO review in accordance with paragraph (d)(1) of this section and who meets the conditions of section 1879(a)(2) of the Social Security Act (that is, the individual did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under part A or part B) may remain in the hospital with no additional financial liability until the QIO makes its determination.

(b) *When delivery of the notice is valid.* (1) Except as provided in paragraph (b)(2) of this section, valid delivery of the notice of non-coverage requires that the beneficiary (or the beneficiary's authorized representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents.

(2) If a beneficiary refuses to sign the notice, the provider may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(c) *Beneficiary's right to other review.* (1) A beneficiary who fails to request an expedited determination in accordance with paragraph (d)(1) of this section, and remains in the hospital, may request an expedited review at any time during the course of his or her inpatient hospital stay. The QIO will issue a decision in accordance with paragraph (e)(5)(ii) of this section. The escalation procedures described in

§405.1204(c)(5) and the financial liability rules of paragraph (f)(2) of this section do not apply.

(2) A beneficiary who fails to request an expedited determination in accordance with paragraph (d)(1) of this section, and who is no longer an inpatient in the hospital, may request QIO review within 30 calendar days after receipt of the notice of noncoverage as provided under section 1154(e)(1) or at any time for good cause. The QIO will issue a decision in accordance with paragraph (e)(5)(iii) of this section. The escalation procedures described in §405.1204(c)(5) and the financial liability rules of paragraph (f)(2) of this section do not apply.

(d) *Procedures the beneficiary must follow.* For the expedited appeal process, the following rules apply:

(1) The beneficiary must submit the request for an expedited determination—

(i) To the QIO that has an agreement with the hospital under part 475 of this chapter;

(ii) In writing or by telephone; and

(iii) By noon of the first working day after he or she receives written notice that the hospital has determined that the hospital stay is no longer necessary.

(2) The beneficiary (or his or her authorized representative), upon request by the QIO, must be prepared to discuss the case with the QIO.

(e) *Procedures the QIO must follow.* On the date that the QIO receives the beneficiary's request:

(1) The QIO must notify the hospital that the beneficiary has filed a request for immediate review.

(2) The hospital must supply any information, including medical records, that the QIO requires to conduct its review and must make it available, by phone or in writing, by the close of business of the first full working day after the day the beneficiary receives notice of the planned discharge.

(3) The QIO must examine the pertinent records pertaining to the services.

(4) The QIO must solicit the views of the beneficiary (or the beneficiary's authorized representative) who requested the expedited determination.

(5)(i) When the beneficiary requests an expedited determination in accordance with paragraph (d)(1) of this section, the QIO must make a determination and notify the beneficiary, the hospital, and physician of its determination by close of business of the first working day after it receives all requested pertinent information.

(ii) When the beneficiary does not request an expedited determination in accordance with paragraph (d)(1) of this section, and remains an inpatient in the hospital, the QIO will make a determination and notify the beneficiary, the hospital, and physician of its determination within 2 working days following receipt of the request and pertinent information.

(iii) When the beneficiary does not request an expedited initial determination in accordance with paragraph (d)(1) of this section, and is no longer an inpatient in the hospital, the QIO will make a determination and notify the beneficiary, the hospital, and physician of its determination within 30 calendar days after receipt of the request and pertinent information.

(f) *Coverage during QIO expedited review.* (1) In general, if the beneficiary remains in the hospital after receiving the hospital issued notice of noncoverage, and the hospital, the physician who concurred in the hospital's determination on which the advanced written notice of termination was based, or the QIO subsequently finds that the beneficiary requires an acute level of inpatient hospital care, the beneficiary is not financially responsible for continued care until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence from the physician responsible for the beneficiary's care or the QIO and notifies the beneficiary.

(2) *Timely filing and limitation on liability.* If a beneficiary both files a request for an expedited determination by the QIO in accordance with paragraph (d)(1) of this section, and meets the conditions of section 1879(a)(2) of the Social Security Act (that is, the individual did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under part A or part B), the beneficiary is not financially responsible for inpatient hospital services furnished before noon of

the calendar day after the date the beneficiary (or his or her representative) receives notification (either orally or in writing) of the expedited determination by the QIO.

(3) *Untimely filing*. When a beneficiary does not file a request for an expedited determination by the QIO in accordance with paragraph (d)(1) of this section, that beneficiary may be responsible for charges that extend beyond the date specified on the hospital's advance written notice of termination or as otherwise stated by the QIO.

(4) *Hospital requests expedited review*. When the hospital requests review in accordance with §405.1208, and the QIO concurs with the hospital's decision, a hospital may not charge a beneficiary until the date specified by the QIO.

(g) *Notice of an expedited determination*. (1) When a QIO issues an expedited determination in accordance with paragraph (e)(5) of this section, the QIO must notify the beneficiary, physician, and hospital of its decision, by telephone and subsequently in writing.

(2) A written notice of the expedited determination must contain the following:

(i) The basis for the determination;

(ii) A detailed rationale for the determination;.

(iii) A statement explaining the Medicare payment consequences of the expedited determination and date of liability, if any;

(iv) A statement informing the beneficiary of his or her subsequent appeal rights, and the timeframe for requesting a reconsideration by the QIC.

(h) *Effect of an expedited QIO determination*. The QIO determination is binding upon the beneficiary, physician, and hospital, except in the following circumstances:

(1) *When beneficiary remains in the hospital*. If the beneficiary is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 405.1204. If the beneficiary does not make a request in accordance with paragraph (d)(1) of this section, the timeframes described in § 405.1204(c)(3), the escalation procedures described in § 405.1204(c)(5), and the coverage rule described in § 405.1204(f) will not apply.

(2) *When beneficiary is no longer an inpatient in the hospital*. If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, the determination is subject to the general claims appeal process.

§ 405.1208 Hospital requests expedited QIO review.

(a) *General rule*. If the hospital (acting directly or through its utilization review committee) believes that the beneficiary does not require further inpatient hospital care but is unable to obtain the agreement of the physician, it may request an expedited determination by the QIO.

(b) *Procedures hospital must follow*. (1) The hospital must (acting directly or through its utilization review committee) notify the beneficiary (or his or her representative) that it has requested that review.

(2) The hospital must supply any pertinent information the QIO requires to conduct its review and must make it available by phone or in writing, by close of business of the first full working day immediately following the day the hospital submits the request for review.

(c) *Procedures the QIO must follow*. (1) The QIO must notify the hospital that it has received the request for review and must notify the hospital if it has not received all pertinent records.

(2) The QIO must examine the pertinent records pertaining to the services.

(3) The QIO must solicit the views of the beneficiary in question.

(4) The QIO must make a determination and notify the beneficiary, the hospital, and physician within 2 working days of the hospital's request and receipt of any pertinent information submitted by the hospital.

(d) *Notice of an expedited determination*. (1) When a QIO issues an expedited determination as stated in paragraph (c)(4) of this section, it must notify the beneficiary, physician, and hospital of its decision, by telephone and subsequently in writing.

(2) A written notice of the expedited initial determination must contain the following:

(i) The basis for the determination;.

(ii) A detailed rationale for the determination;

(iii) A statement explaining the Medicare payment consequences of the expedited determination and date of liability, if any; and

(iv) A statement informing the beneficiary of his or her appeal rights and the timeframe for requesting an appeal.

(e) *Effect of an expedited determination.* The expedited determination under this section is binding upon the beneficiary, physician, and hospital, except in the following circumstances:

(1) *When a beneficiary remains in the hospital.* If the beneficiary is still an inpatient in the hospital and is dissatisfied with this determination, he or she may request a reconsideration according to the procedures described in §405.1204. The procedures described in §405.1204 will apply to reconsiderations requested under this section. If the beneficiary does not make a request in accordance with paragraph (d)(1) of this section, the timeframes described in §405.1204(c)(3), the escalation procedures described in §405.1204(c)(5), and the coverage rule described in §405.1204(f) will not apply.

(2) *When a beneficiary is no longer an inpatient in the hospital.* If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, this determination is subject to the general claims appeal process.

Subparts K–Q [Reserved]

Subpart R—Provider Reimbursement Determinations and Appeals

AUTHORITY: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

SOURCE: 39 FR 34515, Sept. 26, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§405.1801 Introduction.

(a) *Definitions.* As used in this subpart:

Administrator means the Administrator or Deputy Administrator of CMS.

Administrator's review means that review provided for in section 1878(f) of the Act (42 U.S.C. 1395oo(f)) and §405.1875.

Board means the Provider Reimbursement Review Board established in accordance with section 1878 of the Act (42 U.S.C. 1395oo) and §405.1845.

Board hearing means that hearing provided for in section 1878(a) of the Act (42 U.S.C. 1395oo(a)), and §405.1835.

Date of filing and *date of submission of materials* mean the day of the mailing (as evidenced by the postmark) or hand-delivery of materials, unless otherwise defined in this subpart.

Date of receipt means the date on the return receipt of ''return receipt requested'' mail, unless otherwise defined in this subpart.

Intermediary determination means the following:

(1) With respect to a provider of services that has filed a cost report under §§413.20 and 413.24(f) of this chapter, the term means a determination of the amount of total reimbursement due the provider, pursuant to §405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report.

(2) With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (part 412 of this chapter), the term means a determination of the total amount of payment due the hospital, pursuant to §405.1803 following the close of the hospital's cost reporting period, under that system for the period covered by the determination.

(3) For purposes of appeal to the Provider Reimbursement Review Board, the term is synonymous with the phrases ''intermediary's final determination'' and ''final determination of the Secretary'', as those phrases are used in section 1878(a) of the Act.

(4) For purposes of §405.376 concerning claims collection activities, the term does not include an action by CMS with respect to a compromise of a Medicare overpayment claim, or termination or suspension of collection action on an overpayment claim, against

a provider or physician or other supplier.

Intermediary hearing means that hearing provided for in § 405.1809.

(b) *General rule*—(1) *Providers.* The principles of reimbursement for determining reasonable cost and prospective payment are contained in parts 413 and 412, respectively, of this chapter. In order to be reimbursed for covered services furnished to Medicare beneficiaries, providers of services are obliged to file cost reports with their intermediaries as specified in § 413.24(f) of this chapter. Where the term ''provider'' appears in this subpart, it includes hospitals paid under the prospective payment system for purposes of applying the appeal procedures described in this subpart to those hospitals.

(2) *Other entities participating in Medicare Part A.* In addition to providers of services whose status as such is indicated in the Act, there are entities (such as health maintenance organizations) that do not meet the statutory test for providers of services, which may also participate in Medicare. These entities are required to file periodic cost reports and are reimbursed on the basis of information furnished in the reports. Although the entities do not qualify for Board review, the rules as set forth in this subpart with respect to intermediary hearings are applicable to the entities to the maximum extent possible, for cost-reporting periods ending on or after December 31, 1971, where the amount of program reimbursement in controversy is at least $1,000.

(c) *Effective dates.* (1) Except as provided in paragraphs (c)(2) and (c)(3) of this section or in § 405.1885(e), this subpart applies to all cost reporting periods ending on or after December 31, 1971, for which reimbursement may be made on a reasonable cost basis.

(2) Sections 405.1835 to 405.1877 apply only to cost reporting periods ending on or after June 30, 1973, for which reimbursement may be made on a reasonable cost basis.

(3) With respect to hospitals under the prospective payment system (see part 412 of this chapter), the appeals procedures in §§ 405.1811 to 405.1877 that apply become applicable with the hospital's first cost reporting period beginning on or after October 1, 1983.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 48 FR 39834, Sept. 1, 1983; 48 FR 45773, Oct. 7, 1983; 49 FR 322, Jan. 3, 1984; 49 FR 23013, June 1, 1984; 51 FR 34793, Sept. 30, 1986; 61 FR 63749, Dec. 2, 1996]

§ 405.1803 Intermediary determination and notice of amount of program reimbursement.

(a) *General requirement.* Upon receipt of a provider's cost report, or amended cost report where permitted or required, the intermediary must within a reasonable period of time (see § 405.1835(b)), furnish the provider and other parties as appropriate (see § 405.1805) a written notice reflecting the intermediary's determination of the total amount of reimbursement due the provider. The intermediary must include the following information in the notice, as appropriate:

(1) *Reasonable cost.* The notice must—

(i) Explain the intermediary's determination of total program reimbursement due the provider on the basis of reasonable cost for the reporting period covered by the cost report or amended cost report; and

(ii) Relate this determination to the provider's claimed total program reimbursement due the provider for this period.

(2) *Prospective payment.* With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (see part 412 of this chapter), the intermediary must include in the notice its determination of the total amount of the payments due the hospital under that system for the cost reporting period covered by the notice. The notice must explain (with appropriate use of the applicable money amounts) any difference in the amount determined to be due, and the amounts received by the hospital during the cost reporting period covered by the notice.

(b) *Requirements for intermediary notices.* The intermediary must include in each notice appropriate references to law, regulations, CMS Rulings, or program instructions to explain why the intermediary's determination of the amount of program reimbursement for

the period differs from the amount the provider claimed. The notice must also inform the provider of its right to an intermediary or Board hearing (see §§405.1809, 405.1811, 405.1815, 405.1835, and 405.1843) and that the provider must request the hearing within 180 days after the date of the notice.

(c) *Use of notice as basis for recoupment of overpayments*. The intermediary's determination contained in its notice is the basis for making the retroactive adjustment (required by §413.64(f) of this chapter) to any program payments made to the provider during the period to which the determination applies, including recoupment under §405.373 from ongoing payments to the provider of any overpayments to the provider identified in the determination. Recoupment is made notwithstanding any request for hearing on the determination the provider may make under §405.1811 or §405.1835.

[48 FR 39834, Sept. 1, 1983, as amended at 49 FR 322, Jan 3, 1984; 51 FR 34793, Sept. 30, 1986; 61 FR 63748, Dec. 2, 1996]

§405.1804 Matters not subject to administrative and judicial review under prospective payment.

Neither administrative nor judicial review is available for controversies about the following matters:

(a) The determination of the requirement, or the proportional amount, of any budget neutrality adjustment in the prospective payment rates.

(b) The establishment of—

(1) Diagnosis related groups (DRGs);

(2) The methodology for the classification of inpatient discharges within the DRGs; or

(3) Appropriate weighting factors that reflect the relative hospital resources used with respect to discharge within each DRG.

[49 FR 322, Jan. 1, 1984]

§405.1805 Parties to intermediary determination.

The parties to the intermediary's determination are the provider and any other entity found by the intermediary to be a related organization of the provider under §413.17 of this chapter.

[48 FR 39835, Sept. 1, 1983, as amended at 51 FR 34793, Sept. 30, 1986]

§405.1807 Effect of intermediary determination.

The determination shall be final and binding on the party or parties to such determination unless:

(a) An intermediary hearing is requested in accordance with §405.1811 and an intermediary hearing decision rendered in accordance with §405.1831; or

(b) The intermediary determination is revised in accordance with §405.1885; or

(c) A Board hearing is requested in accordance with §405.1835 and a hearing decision rendered pursuant thereto.

§405.1809 Intermediary hearing procedures.

(a) *Hearings*. Each intermediary must establish and maintain written procedures for intermediary hearings, in accordance with the regulations in this subpart, for resolving issues that may arise between the intermediary and a provider concerning the amount of reasonable cost reimbursement, or prospective payment due the provider (except as provided in §405.1804) under the Medicare program. The procedures must provide for a hearing on the intermediary determination contained in the notice of program reimbursement (§405.1803), if the provider files a timely request for a hearing.

(b) *Amount in controversy*. In order for an intermediary to grant a hearing, the following dates and amounts in controversy apply:

(1) For cost reporting periods ending prior to June 30, 1973, the amount of program reimbursement in controversy must be at least $1000.

(2) For cost reporting periods ending on or after June 30, 1973, the amount of program reimbursement in controversy must be at least $1000 but less than $10,000.

[48 FR 39835, Sept. 1, 1983, as amended at 49 FR 323, Jan. 1, 1984]

§405.1811 Right to intermediary hearing; time, place, form, and content of request for intermediary hearing.

(a) A provider that has been furnished a notice of amount of program reimbursement may request an intermediary hearing if it is dissatisfied with the intermediary's determination

contained in the notice and the amount in controversy requirement described in § 405.1809 is met. The request must be in writing and be filed with the intermediary within 180 calendar days after the date of the notice. (See § 405.1835(c)). No other individual, entity, or party has the right to an intermediary hearing.

(b) The request must (1) identify the aspect(s) of the determination with which the provider is dissatisfied, and (2) explain why the provider believes the determination on these matters is incorrect, and (3) be submitted with any documentary evidence the provider considers necessary to support its position.

(c) Following the timely filing of the request for hearing, the provider may identify in writing, prior to the onset of the hearing proceedings, additional aspects of the determination with which it is dissatisfied and furnish any documentary evidence in support thereof. If such additional aspects are submitted, the hearing officer may postpone the hearing to allow for his examination of such additional aspects.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 48 FR 39835, Sept. 1, 1983]

§ 405.1813 Failure to timely request an intermediary hearing.

If a provider requests an intermediary hearing on an intermediary's determination after the time limit prescribed in § 405.1811, the designated intermediary hearing officer or panel of hearing officers will dismiss the request and furnish the provider a written notice that explains the time limitation, except that for good cause shown, the time limit prescribed in § 405.1811 may be extended. However, an extension may not be granted if the extension request is filed more than 3 years after the date of the original notice of the intermediary determination.

[48 FR 39835, Sept. 1, 1983]

§ 405.1815 Parties to the intermediary hearing.

The parties to the intermediary hearing shall be the parties to the intermediary determination and any other entity determined by the intermediary to be a related organization of such provider. Said parties shall be given reasonable notice of the time, date, and place of such hearing. Neither the intermediary nor the Centers for Medicare & Medicaid Services are parties (see § 405.1819).

§ 405.1817 Hearing officer or panel of hearing officers authorized to conduct intermediary hearing; disqualification of officers.

The intermediary hearing provided for in § 405.1809 shall be conducted by a hearing officer or panel of hearing officers designated by the intermediary. Such hearing officer or officers shall be persons knowledgeable in the field of health care reimbursement. The hearing officer or officers shall not have had any direct responsibility for the program reimbursement determination with respect to which a request for hearing is filed; no hearing officer (or officers) shall conduct a hearing in a case in which he is prejudiced or partial with respect to any party, or where he has any interest in the matter pending for determination before him. Notice of any objection which a party may have with respect to a hearing officer shall be presented in writing to such officer by the objecting party at the party's earliest opportunity. The hearing officer shall consider the objection and shall, at his discretion, either proceed in the conduct of the hearing or withdraw. If the hearing officer does not withdraw, the objecting party may, after the hearing, present his objections to an executive official of the intermediary, who shall rule promptly on the objection.

§ 405.1819 Conduct of intermediary hearing.

The hearing shall be open to all parties thereto (see § 405.1815) and to representatives of the intermediary and of the Centers for Medicare & Medicaid Services (see § 405.1815). The hearing officer(s) shall inquire fully into all of the matters at issue and shall receive into evidence the testimony and any documents which are relevant and material to such matters. If the hearing officer(s) believes that there is relevant and material evidence available which has not been presented at the hearing,

he (they) may, at any time prior to the mailing of notice of the decision, reopen the hearing record for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the hearing officer(s).

§405.1821 Prehearing discovery and other proceedings prior to the intermediary hearing.

(a) Prehearing discovery shall be permitted upon timely request of any party. To be timely, a request for discovery and inspection shall be made before the beginning of the hearing. A reasonable time for inspection and reproduction of documents shall be provided by order of the hearing officer(s).

(b) If, in the discretion of the hearing officer(s), the purpose of defining the issues more clearly would be served, the hearing officer(s) may schedule a prehearing conference. For this purpose, a single member of a panel of hearing officers, when such is the case, may be appointed to act for the panel with respect to prehearing activities.

§405.1823 Evidence at intermediary hearing.

Evidence may be received at the intermediary hearing even though inadmissible under the rules of evidence applicable to court procedure. The hearing officer(s) shall give the parties opportunity for submission and consideration of facts and arguments, and during the course of the hearing, should in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The hearing officer(s) shall render a final ruling on the admissibility of evidence.

§405.1825 Witnesses at intermediary hearing.

The hearing officer(s) may examine the witnesses and shall allow the parties and their representatives to do so. Parties to the proceedings may also cross-examine witnesses.

§405.1827 Record of intermediary hearing.

A complete recordation of the proceedings at the intermediary hearing shall be made and transcribed in all cases. It shall be made available to any party upon request. The record will not be closed until a decision (see §405.1831) has been issued.

§405.1829 Authority of hearing officer(s) at intermediary hearing.

(a) The hearing officer(s) in exercising his authority must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with CMS Rulings issued under the authority of the Administrator of the Centers for Medicare & Medicaid Services (see 42 CFR 401.108), and with the general instructions issued by the Centers for Medicare & Medicaid Services in accordance with the Secretary's agreement with the intermediary.

(b) The determination of a fiscal intermediary that no payment may be made under title XVIII of the Act for any expense incurred for items and services furnished to an individual because such items and services are excluded from coverage pursuant to section 1862 of the Act, 42 U.S.C. 1395y (see subpart C of this part), shall not be reviewed by the hearing officer(s). Such determination shall be reviewed only in accordance with the applicable provisions of subparts G and H of this part.

§405.1831 Intermediary hearing decision and notice.

The hearing officer(s) shall, on a timely basis, render a decision in writing based on the evidence in the record; such decision shall constitute the final determination of the intermediary. In such decision, he will cite applicable law, regulations, CMS Rulings, and general instructions of the Centers for Medicare & Medicaid Services, as well as findings on all the matters in issue at the hearing. A copy of the decision will be mailed to all parties to the hearing at their last known addresses.

§405.1833 Effect of intermediary hearing decision.

The intermediary hearing decision provided for in §405.1831 shall be final and binding upon all parties to the

hearing unless such intermediary determination is revised in accordance with § 405.1885.

§ 405.1835 Right to Board hearing.

(a) *Criteria.* The provider (but no other individual, entity, or party) has a right to a hearing before the Board about any matter designated in § 405.1801(a)(1), if:

(1) An intermediary determination has been made with respect to the provider; and

(2) The provider has filed a written request for a hearing before the Board under the provisions described in § 405.1841(a)(1); and

(3) The amount in controversy (as determined in § 405.1839(a)) is $10,000 or more.

(b) *Prospective payment exceptions.* Except with respect to matters for which administrative or judicial review is not permitted as specified in § 405.1804, hospitals that are paid under the prospective payment system are entitled to hearings before the Board under this section if they otherwise meet the criteria described in paragraph (a) of this section.

(c) *Right to hearing based on late intermediary determination about reasonable cost.* Notwithstanding the provisions of paragraph (a)(1) of this section, the provider also has a right to a hearing before the Board if an intermediary's determination concerning the amount of reasonable cost reimbursement due a provider is not rendered within 12 months after receipt by the intermediary of a provider's perfected cost report or amended cost report (as permitted or as required to furnish sufficient data for purposes of making such determination—see § 405.1803(a)) provided such delay was not occasioned by the fault of the provider.

[48 FR 39835, Sept. 1, 1983]

§ 405.1837 Group appeal.

(a) *Criteria for group appeals.* Subject to paragraph (b) of this section, a group of providers may bring an appeal before the Board but only if—

(1) Each provider in the group is identified as one which would, upon the filing of a request for a hearing before the Board, but without regard to the $10,000 amount in controversy requirement, be entitled to a hearing under § 405.1835;

(2) The matters at issue involve a common question of fact or of interpretation of law, regulations or CMS Rulings; and

(3) The amount in controversy is, in the aggregate, $50,000 or more.

(b) *Providers under common ownership or control.* Effective April 20, 1983, any appeal filed by providers that are under common ownership or control must be brought by the providers as a group appeal in accordance with the provisions of paragraph (a) of this section with respect to any matters involving an issue common to the providers and for which the amount in controversy is, in the aggregate, $50,000 or more (see § 405.1841(a)(2)). A single provider involved in a group appeal that also wishes to appeal issues that are not common to the other providers in the group must file a separate hearing request (see § 405.1841(a)(1)) and must separately meet the requirements in § 405.1811 or § 405.1835, as applicable.

[48 FR 39836, Sept. 1, 1983]

§ 405.1839 Amount in controversy.

(a) *Single appeals.* The $1,000 amount in controversy required under § 405.1809 for an intermediary hearing and the $10,000 amount in controversy required under § 405.1835 for a Board hearing is, as applicable to the matters for which the provider has requested a hearing, the combined total of the amounts computed as follows:

(1) *Providers under prospective payment.* For providers that are paid under the prospective payment system, by deducting—

(i) The total of the payment due the provider on other than a reasonable cost basis under the prospective payment system from the total amount that would be payable after a recomputation that takes into account any exclusion, exception, adjustment, or additional payment denied the provider under part 412 of this chapter, as applicable;

(ii) The total of the payment due the provider on a reasonable cost basis under the prospective payment system from the total reimbursable costs claimed by the provider; and

(iii) The adjusted total reimbursable costs due the provider on a reasonable cost basis under other than the prospective payment system from the total reimbursable costs claimed by the provider.

(2) *Providers not under prospective payment.* For providers that are not paid under the prospective payment system, by deducting the adjusted total reimbursable program costs due the provider on a reasonable cost basis from the total reimbursable costs claimed by the provider.

(b) *Group appeals.* The $50,000 amount in controversy required under §405.1837 for group appeals to the Board is, as applicable to the common matters for which the group of providers have requested a hearing, the combined total of the amounts computed as follows:

(1) *Providers under prospective payment.* For providers that are paid under the prospective payment system, by deducting—

(i) The total of the payment due the providers (in the aggregate) on other than a reasonable cost basis under the prospective payment system from the total amount that would be payable to the providers (in the aggregate) after a recomputation that takes into account any applicable exception, exclusion, adjustment, or additional payment denied the providers under part 412 of this chapter.

(ii) The total of the payment due the providers (in the aggregate) on a reasonable cost basis under the prospective payment system from the total reimbursable costs claimed in the aggregate by the providers; and

(iii) The adjusted total reimbursable costs due the providers (in the aggregate) on a reasonable cost basis under other than the prospective payment system from the total reimbursable costs claimed in the aggregate by the providers.

(2) *Providers not under prospective payment.* For providers that are not paid under the prospective payment system, by deducting the adjusted total reimbursable program costs due the providers (in the aggregate) on a reasonable cost basis from the total reimbursable costs claimed in the aggregate by the providers.

[49 FR 323, Jan. 3, 1984]

§405.1841 Time, place, form, and content of request for Board hearing.

(a) *General requirements.* (1) The request for a Board hearing must be filed in writing with the Board within 180 days of the date the notice of the intermediary's determination was mailed to the provider or, where notice of the determination was not timely rendered, within 180 days after the expiration of the period specified in §405.1835(c). Such request for Board hearing must identify the aspects of the determination with which the provider is dissatisfied, explain why the provider believes the determination is incorrect in such particulars, and be accompanied by any documenting evidence the provider considers necessary to support its position. Prior to the commencement of the hearing proceedings, the provider may identify in writing additional aspects of the intermediary's determination with which it is dissatisfied and furnish any documentary evidence in support thereof.

(2) Effective April 20, 1983, any request for a Board hearing by providers that are under common ownership or control (see §413.17 of this chapter) must be brought by the providers as a group appeal (see §405.1837(b)) with respect to any matters at issue involving a question of fact or of interpretation of law, regulations, or CMS Rulings common to the providers and for which the amount in controversy is $50,000 or more in the aggregate. If a group appeal is filed, the provider seeking the appeal must be separately identified in the request for hearing, which must be prepared and filed consistently with the requirements of paragraph (a)(1) of this section.

(b) *Extension of time limit for good cause.* A request for a Board hearing filed after the time limit prescribed in paragraph (a) of this section shall be dismissed by the Board, except that for good cause shown, the time limit may be extended. However, no such extension shall be granted by the Board if such request is filed more than 3 years after the date the notice of the intermediary's determination is mailed to the provider.

[48 FR 39836, Sept. 1, 1983, as amended at 51 FR 34793, Sept. 30, 1986]

§ 405.1842 Expediting Board proceedings.

(a) *Basis and purpose.* This section implements section 1878(f)(1) of the Social Security Act, as amended by section 955 of Public Law 96–499 (42 U.S.C. 1395oo(f)(1)). The amendment provides an opportunity for providers to obtain expedited administrative review when the Board determines that it does not have the authority to decide a question of law, regulation, or CMS Ruling relevant to the case (see § 405.1867).

(b) *Basic rule.* (1) Except as provided in paragraph (b)(4) of this section, a provider may submit a written request to the Board, with supporting documentation, to determine whether the Board has the authority to decide a question of law, regulations, or CMS Rulings relevant to and controlling upon an issue to be reviewed by the Board. The Board is required to make an expedited review determination in writing, either denying or granting the request, within 30 days after the date of receipt of the request, as defined in paragraph (1) of this section. The Board may also issue a determination on its own motion that it lacks authority to decide a question of law, regulations or CMS Rulings.

(2) The Board must determine that the provider (including each provider in a group appeal) is entitled to a hearing under section 1878(a) of the Act before making the determination described in paragraph (b)(1) of this section. Thus, the provider must file (or have already filed) a written request for a Board hearing that meets the requirements in § 405.1841. The information and documentation required with respect to the filing of a request for a hearing is used by the Board to determine jurisdiction under section 1878(a) of the Act.

(3) A provider's request for an expedited review determination cannot be considered to be filed with the Board, nor can the 30-day time period during which the Board is required to make an expedited review determination begin, until such time as the Board accepts jurisdiction of the case.

(4) Proceedings conducted by the Board under an authority other than section 1878(a) of the Act and §§ 405.1835 through 405.1873 of this subpart are not hearings for purposes of this section and are not subject to the expedited Board proceedings set forth in this section. For example, proceedings concerning reimbursement for capital expenditures conducted under section 1122(f) of the Act and § 405.1890 of this subpart are not hearings for purposes of this section. (Section 1122(f) specifically bars any administrative or judicial review.)

(c) *''Own motion'' review.* If the Board is considering issuing a determination on its own motion that it lacks the authority to decide a question of law, regulations, or CMS Rulings, it will notify the provider and intermediary of its proposed determination and allow them a reasonable period of time to file evidence or arguments either to support or oppose the proposed determination.

(d) *Provider requests.* (1) If a provider seeks an expedited Board proceeding, it must—(i) File its appropriately documented request in writing with the Board; and

(ii) Send a copy of the request and documentation simultaneously to the intermediary.

(2) The request to the Board for an expedited review determination must—(i) Identify the issues and the controlling law, regulation or CMS Ruling for which the Board is to make a determination;

(ii) Allege and demonstrate that there are no factual issues in dispute;

(iii) Contain an explanation of why the provider believes the Board cannot decide the legal issue or issues that are in dispute; and

(iv) Include all other information or details that support the request.

(3) If the information in the provider request is insufficient for the Board to determine whether it has the authority to decide an issue, the Board will request more information from the provider. Such a request will affect the 30-day time limit as provided in paragraph (i) of this section. If the provider does not send more information or sends inadequate information, the Board will determine that it has the authority to decide the issue and will begin the regular procedure for a hearing.

(e) *Intermediary participation.* (1) After receiving a copy of the provider's request for an expedited review determination, the intermediary may send comments to the Board on the provider's request and supporting documentation. The intermediary will send a copy of its comments to the provider simultaneously.

(2) If the intermediary's comments raise questions about the provider's request for expedited review, the Board may request additional information from the provider as provided in paragraph (d)(3) of this section.

(f) *Criteria for a Board determination.* The Board will review all documentation forwarded by the provider and the intermediary relevant to the request for a Board determination concerning the Board's authority to decide an issue. In its review, the Board will consider—

(1) The controlling facts in the case;

(2) The applicability of law, regulations, or CMS rulings;

(3) Whether there are factual issues for the Board to resolve; and

(4) Whether there are legal issues within the authority of the Board to decide.

(g) *Board determination.* (1) Within 30 days after the date of receipt (as defined in paragraph (i) of this section) of a provider's request and all necessary documentation the Board will issue a determination concerning its authority to decide the question of law, regulations, or CMS Rulings relevant to the issues identified by the provider in its request.

(2) If there are factual or legal issues in dispute on an issue within the authority of the Board to decide, the Board will not make an expedited review determination on the particular issue but will proceed with a hearing. The Board has the authority to decide when two or more issues are sufficiently related to preclude separation for purposes of an expedited review determination on one or more of them and a hearing on the other or others.

(3) The Board will promptly notify the provider in writing of its determination and will send a copy of the determination to the intermediary.

(4) The Board's determination concerning its authority or its lack of a determination is not subject to the Secretary's review under §405.1875.

(h) *Effect of a Board decision.* (1) The Board's determination, issued on its own motion or at the request of a provider, that it lacks authority to decide a question of law, regulations or CMS Rulings is a final decision permitting a provider to seek judicial review with respect to the matter or matters in controversy contained in the determination, within 60 days of the date of the Board's determination.

(2) After the Board has determined that it does not have the authority to decide an issue, the provider will not be granted a hearing on the same issue.

(3) If the Board fails to issue an expedited review determination within 30 days of the date of receipt of a complete request (as determined under paragraph (i) of this section), the provider may, within 60 days from the end of that period, seek judicial review of the matters for which it requested the Board's determination.

(4) If the Board fails to make an expedited review determination within the required 30 days, it will begin regular hearing procedures as though it has the authority to decide the issue.

(5) If the provider seeks judicial review because the Board fails to make a determination as provided in paragraph (g)(1) of this section, it should notify the Board at the time it files for judicial review. The Board will not hold a hearing, even if one has been scheduled, on the matter or matters for which the provider is seeking judicial review.

(6) The Board's determination does not affect the right of the provider to a Board hearing for issues for which the provider did not request expedited review, or for which the Board determines it does have the authority to decide, or for which the Board did not make a determination and the provider did not request judicial review.

(i) *Date of receipt.* For purposes of this section, the date of receipt of the provider's request is the later of—

(1) The actual date of receipt by the Board of the information required under paragraph (d)(2) of this section, or of additional information requested by the Board under paragraph (d)(3) of

this section, whichever the Board receives later; or

(2) The date indicated on the Board's written notification to the provider that the Board has accepted jurisdiction of the case.

(j) *Examples*. Below are examples showing when a provider may expect to receive an expedited review determination, in relation to various circumstances affecting its request for the determination.

(1) The provider requests a hearing and expedited review at or about the same time. If all information is complete, the Board could send notification that it has accepted jurisdiction of the case and the expedited review determination simultaneously.

(2) The provider requests both a hearing and an expedited review determination, and supplies complete information. The Board accepts jurisdiction but, for example, because of the complexity of the case, the Board makes its expedited review determination within 30 days after it has accepted jurisdiction.

(3) The provider requests both a hearing and an expedited review determination, but the request for a hearing does not contain enough information for the Board to determine jurisdiction. The Board would request more information to determine jurisdiction and would make its expedited review determination within 30 days after it has accepted jurisdiction.

(4) The provider requests both a hearing and an expedited review determination, but does not send enough information for the Board to make an expedited review determination. Assuming the Board accepts jurisdiction, the Board would request more information about the request for expedited review and make its determination within 30 days after it receives the additional information.

(5) The provider requests an expedited review determination after the Board has accepted jurisdiction. The Board would make its determination within 30 days after receipt of an appropriately documented request for an expedited review determination.

[47 FR 31690, July 22, 1982, as amended at 48 FR 22925, May 23, 1983]

§ 405.1843 Parties to Board hearing.

(a) The parties to the Board hearing shall be the provider, the intermediary (including the Centers for Medicare & Medicaid Services when acting directly as intermediary) that rendered the determination being appealed (see § 405.1833), and any other entity found by the intermediary to be a related organization of such provider.

(b) Except as provided in paragraph (a), neither the Secretary nor the Centers for Medicare & Medicaid Services may be made a party to the hearing. However, the Board may call as a witness any employee or officer of the Department of Health and Human Services having personal knowledge of the facts and the issues in controversy in a hearing pending before the Board and may call as a consultant to the Board in connection with any such hearing any individual designated by the Secretary for such purpose. (See § 405.1863.)

§ 405.1845 Composition of Board.

(a) The Board will consist of five members appointed by the Secretary. All shall be knowledgeable in the field of cost reimbursement. At least one shall be a certified public accountant. Two Board members shall be representative of providers of services.

(b) The term of office for Board members shall be 3 years, except that initial appointments may be for such shorter terms as the Secretary may designate to permit staggered terms of office. No member shall serve more than two consecutive 3-year terms of office. The Secretary shall have the authority to terminate a Board member's term of office for good cause.

(c) One member of the Board shall be designated by the Secretary as Chairman thereof and shall coordinate and direct the administrative activities of the Board, and shall have such other authority which may be granted to him by the Board.

(d) A quorum shall be required for the rendering of Board decisions. Three members, at least one of whom is representative of providers of services, shall be required to constitute a quorum. The Chairman of the Board, with approval of the provider, may designate one or more Board members to conduct any hearing and to prepare a

recommended decision (where less than a quorum conducts the hearing). (See § 405.1869.)

[39 FR 34515, Sept. 26, 1974, as amended at 41 FR 52051, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.1847 Disqualification of Board members.

No Board member shall join in the conduct of a hearing in a case in which he is prejudiced or partial with respect to any party or in which he has any interest in the matter pending for decision before him. Notice of any objection which a party may have with respect to a Board member shall be presented in writing to such Board member by the objecting party at its earliest opportunity. The Board member shall consider the objection and shall, in his discretion, either proceed to join in the conduct of the hearing or withdraw. If he does not withdraw, the objecting party may petition the Board, presenting its objection and reasons therefor, and be entitled to a ruling thereon before the hearing can proceed.

§ 405.1849 Establishment of time and place of hearing by the Board.

The Board shall fix the time and place for the hearing and shall mail written notice thereof to the parties at their last known addresses, not less than 30 days prior to the scheduled time. Either on its own motion or for good cause shown by a party, the Board may, as appropriate, reschedule, adjourn, postpone, or reopen the hearing, provided that reasonable written notice is given to the parties.

§ 405.1851 Conduct of Board hearing.

The Board hearing shall be open to the parties, to representatives of the Centers for Medicare & Medicaid Services, and to such other persons as the Board deems necessary and proper. The Board shall inquire fully into all of the matters at issue and shall receive into evidence the testimony of witnesses and any documents which are relevant and material to such matters. If the Board believes that there is relevant and material evidence available which has not been presented at the hearing, it may at any time prior to the mailing of notice of the decision, reconvene the hearing for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the Board.

§ 405.1853 Prehearing discovery and other proceedings prior to the Board hearing.

(a) Upon notification that a request for Board hearing has been filed, the intermediary shall forthwith review the materials submitted by the provider in accordance with § 405.1841. Simultaneously, the intermediary shall review the information which formed the basis for its determination of the amount of program reimbursement. Based on the findings of such review, the intermediary shall expeditiously attempt to join with the provider in written stipulations setting forth the issues that said review has resolved and designating the issues that remain for Board resolution. Having obtained such stipulations and being satisfied that no further agreements can be negotiated, the intermediary shall ensure that all available documentary evidence in support of each party's position is part of the record. Such evidence will ordinarily include a position paper from the provider, a position paper from the intermediary, and any documents which support the issues addressed in the stipulations. These materials, in addition to all relevant documents which formed the basis for its determination of the amount of program reimbursement, shall be forwarded to the Board within 60 days after the date of the provider's request for Board review.

(b) Prehearing discovery shall be permitted upon timely request of a party. To be timely, a request for discovery and inspection shall be made before the beginning of the hearing. A reasonable time for inspection and reproduction of documents shall be provided by order of the Board. The Board's order on all discovery matters shall be final.

(c) If, in the discretion of the Board, the purpose of defining the issues more clearly would be served, the Board may schedule a prehearing conference. For this purpose, a single member of the Board may be appointed to act for the

Board with respect to prehearing activities.

§ 405.1855 Evidence at Board hearing.

Evidence may be received at the Board hearing even though inadmissible under the rules of evidence applicable to court procedure. The Board shall give the parties opportunity for submission and consideration of facts and arguments and during the course of the hearing should, in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The Board shall render a final ruling on the admissibility of evidence.

§ 405.1857 Subpoenas.

When reasonably necessary for the full presentation of a case, the Board may, either upon its own motion or upon the request of a party, issue subpoenas for the attendance and testimony of witnesses and for the production of books, records, correspondence, papers, or other documents which are relevant and material to any matter in issue at the hearing. Parties who desire the issuance of a subpoena shall, not less than 10 days prior to the time fixed for the hearing, file with the Board a written request therefor, designating the witnesses or documents to be produced, and describing the address, or location thereof with sufficient particularity to permit such witnesses or documents to be found. The request for a subpoena shall state the pertinent facts which the party expects to establish by such witnesses or documents and whether such facts could be established by other evidence without the use of a subpoena. Subpoenas, as provided for above, shall be issued in the name of the Board, and the Centers for Medicare & Medicaid Services shall assume the cost of the issuance and the fees and mileage of any witness so subpoenaed, as provided in section 205(d) of the Act, 42 U.S.C. 405(d).

§ 405.1859 Witnesses.

Witnesses at the hearing shall testify under oath or affirmation, unless excused by the Board for cause. The Board may examine the witnesses and shall allow the parties or their representatives to do so. Parties to the proceeding may also cross-examine witnesses.

§ 405.1861 Oral argument and written allegations.

The parties, upon their request, shall be allowed a reasonable time for the presentation of oral argument or for the filing of briefs or other written statements of allegations as to facts or law. Copies of any brief or other written statement shall be filed in sufficient number that they may be made available to all parties and to the Centers for Medicare & Medicaid Services.

§ 405.1863 Administrative policy at issue.

Where a party to the Board hearing puts into issue an administrative policy which is interpretative of the law or regulations, the Board will promptly notify to the Centers for Medicare & Medicaid Services.

§ 405.1865 Record of Board hearing.

A complete record of the proceedings at the hearing shall be made and transcribed in all cases. It shall be made available to the parties upon request. The record will not be closed until a decision has been issued.

§ 405.1867 Sources of Board's authority.

In exercising its authority to conduct the hearings described herein, the Board must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as CMS Rulings issued under the authority of the Administrator of the Centers for Medicare & Medicaid Services (see § 401.108 of this subchapter). The Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

[48 FR 22925, May 23, 1983]

§ 405.1869 Scope of Board's decision-making authority.

The Board shall have the power to affirm, modify, or reverse a determination of an intermediary with respect to a cost report and to make any other modifications on matters covered by

such cost report (including modifications adverse to the provider or other parties) even though such matters were not considered in the intermediary's determination. The opinion of the majority of those Board members deciding the case will constitute the Board's decision.

§ 405.1871 Board hearing decision and notice.

(a) The Board shall, as soon as practicable after the conclusion of its hearing, render a written decision based upon the record made at such hearing, the record established in support of the determination of the intermediary (see § 405.1803), and such other evidence as may be obtained or received by the Board. Such Board decision shall be supported by substantial evidence when the record of the Board hearing is viewed as a whole and shall cite applicable law, regulations, and CMS Rulings. A copy of the decision shall be mailed to all parties to the hearing at their last known addresses and, at the same time, to the Administrator and CMS.

(b) The decision of the Board provided for in paragraph (a) of this section shall be final and binding upon all parties to the hearing before the Board unless it is reviewed by the Secretary in accordance with § 405.1875, or revised in accordance with § 405.1885.

[39 FR 34515, Sept. 26, 1974, as amended at 41 FR 52051, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 48 FR 45773, Oct. 7, 1983]

§ 405.1873 Board's jurisdiction.

(a) *Board decides jurisdiction.* The Board decides questions relating to its jurisdiction to grant a hearing, including (1) the timeliness of an intermediary determination (see § 405.1835(c)), and (2) the right of a provider to a hearing before the Board when the amount in controversy is in issue (see §§ 405.1835(a)(3) and 405.1837).

(b) *Matters not subject to board review.* (1) The determination of a fiscal intermediary that no payment may be made under title XVIII of the Act for any expenses incurred for items and services furnished to an individual because such items and services are excluded from coverage pursuant to section 1862 of the Act, 42 U.S.C. 1395y (see subpart C of this part), may not be reviewed by the Board. (Such determination shall be reviewed only in accordance with the applicable provisions of subpart G or H of this part.)

(2) The Board may not review certain matters affecting payments to hospitals under the prospective payment system as provided in § 405.1804.

[48 FR 39836, Sept. 1, 1983]

§ 405.1875 Administrator's review.

(a) *General rule.* (1) Except for a Board determination under § 405.1842 that it lacks the authority to decide an issue, the Administrator, at his or her discretion, may review any final decision of the Board, including a decision under § 405.1873 about the Board's jurisdiction to grant a hearing. The Administrator may exercise this discretion on his or her own motion, in response to a request from a party to a Board hearing or in response to a request from CMS.

(2) The Office of the Attorney Advisory will examine the Board's decisions, the requests made by a party or CMS and any submission made in accordance with the provisions of this section in order to assist the Administrator in deciding whether to exercise this review authority.

(b) *Request for review.* A party or CMS requesting the Administrator to review a Board decision must file a written request with the Administrator within 15 days of the receipt of the Board decision.

(c) *Criteria for deciding whether to review.* In deciding whether to review a Board decision, either on his or her own motion or in response to a request from a party to the hearing or CMS, the Administrator will normally consider whether it appears that:

(1) The Board made an erroneous interpretation of law, regulation or CMS Ruling;

(2) The Board's decision is not supported by substantial evidence; or

(3) The case presents a significant policy issue having a basis in law and regulations, and review is likely to lead to the issuance of a CMS Ruling or other directive needed to clarify a statutory or regulatory provision;

(4) The Board has incorrectly assumed or denied jurisdiction or extended its authority to a degree not provided for by statute, regulation or CMS Ruling; and

(5) The decision of the Board requires clarification, amplification, or an alternative legal basis for the decision.

(d) *Decision to review.* (1) Whether or not a party or CMS has requested review, the Administrator will promptly notify the parties and CMS whether he or she has decided to review a decision of the Board and, if so, will indicate the particular issues he or she will consider.

(2) The Administrator may decline to review a case or any issue in a case even if a party has filed a written request for review under paragraph (b) of this section.

(e) *Written submissions.* (1) Within 15 days of receipt of a notice that the Administrator has decided to review a Board decision, a party or CMS may submit to the Administrator, in writing:

(i) Proposed findings and conclusions;

(ii) Supporting views or exceptions to the Board decision;

(iii) Supporting reasons for the exceptions and proposed findings; and

(iv) A rebuttal of the other party's request for review or other submissions already filed with the Administrator.

(2) These submissions shall be limited to issues the Administrator has decided to review and confined to the record of the Board hearing.

(3) A party or CMS, within 15 days of receipt of a notice that the Administrator has decided to review a decision, may also request that the decision be remanded and state reasons for doing so. Reasons for a request to remand may include new, substantial evidence concerning—

(i) Issues presented to the Board; and

(ii) New issues that have arisen since the case was presented to the Board.

(4) A copy of any written submission made under this paragraph shall be sent simultaneously to each other party to the Board hearing and to CMS, if CMS has previously—

(i) Requested that the Administrator review a Board decision or filed a written submission in response to a party's request for review.

(ii) Responded to a party's request for review; or

(iii) Submitted material after the Administrator has announced that he or she will review a Board decision.

(f) *Ex parte communications prohibited.* All communications from any of the parties or CMS about a Board decision being reviewed by the Administrator must be in writing and must contain a certification that copies have been served on the parties and CMS, as appropriate. The Administrator will not consider any communication that does not meet these requirements or is not submitted within the required time limits.

(g) *Administrator's decision.* (1) If the Administrator has notified the parties and CMS that he or she has decided to review a Board decision, the Administrator will affirm, reverse, modify or remand the case.

(2) The Administrator will make this decision within 60 days after the provider received notification of the Board decision and will promptly mail a copy of the decision to each party and to CMS.

(3) Any decision other than to remand will be confined to—

(i) The record of the Board, as forwarded by the Board;

(ii) Any materials submitted under paragraphs (b) or (e) of this section; and

(iii) Generally known facts that are not subject to reasonable dispute.

(4) The Administrator may rely on prior decisions of the Board, the Administrator and the courts, and other applicable law, whether or not cited by the parties and CMS.

(h) *Remand.* (1) A remand to the Board by the Administrator vacates the Board's decision.

(2) The Administrator may direct the Board to take further action with respect to the development of additional facts or new issues, or to consider the applicability of laws or regulations other than those considered by the Board. The following are not acceptable bases for remand—

(i) Presentation of evidence existing at the time of the Board hearing that was known or reasonably could have been known;

(ii) Introduction of a favorable court case that was either not available in print at the time of the Board hearing or was decided after the Board hearing;

(iii) Change of a party's representation before the Board;

(iv) Presentation of an alternative legal basis concerning an issue in dispute; or

(v) Attempted retraction of a waiver of a right made before or at the Board hearing.

(3) After remand, the Board will take the action requested in the remand action and issue a new decision.

(4) The new decision will be final unless the Administrator reverses, affirms, modifies, or again remands the decision in accordance with the provisions of the section.

[48 FR 45773, Oct. 7, 1983]

§ 405.1877 Judicial review.

(a) *General rule.* Section 1878(f) of the Act permits a provider to obtain judicial review of a final decision of the Board, or of a reversal, affirmation, or modification by the Administrator of a Board decision, by filing a civil action pursuant to the Federal Rules of Civil Procedure within 60 days of the date on which the provider received notice of—

(1) A final decision by the Board; or

(2) Any reversal, affirmance, or modification by the Administrator.

The Board's decision is not final if the Administrator reverses, affirms or modifies the decision within 60 days of the date on which the provider received notice of the decision.

(b) *Administrator declines to review a Board decision.* If the Administrator declines to review a Board decision, the provider must file its appeal within 60 days of receipt of the decision of the Board.

(c) *Administrator does not act after reviewing a Board decision.* If the Administrator notifies the parties that he or she has decided to review a Board decision and then does not make a decision within the 60 days allotted for his or her review, this subsequent inaction constitutes an affirmance allowing a provider an additional 60 days in which to file for judicial review, beginning with the date the Administrator's time expires for taking action under § 405.1875(g)(2).

(d) *Matters not subject to judicial review.* Certain matters affecting payments to hospital under the prospective payment system are not subject to judicial review, as provided in section 1886(d)(7) of the Act and § 405.1804.

(e) *Group appeals.* Any action under this section by providers that are under common ownership or control (see § 413.17 of this chapter) must be brought by the providers as a group with respect to any matter involving an issue common to the providers.

(f) *Venue for appeals.* An action for judicial review must be brought in the District Court of the United States for the judicial district in which the provider is located (or, effective April 20, 1983, in an action brought jointly by several providers, the judicial district in which the greatest number of such providers are located) or in the District Court for the District of Columbia. Effective April 20, 1983, any action for judicial review by providers under common ownership or control (§ 413.17 of this chapter), must be brought by such providers as a group with respect to any matter involving an issue common to the providers.

(g) *Service of process.* Process must be served as described under 45 CFR part 4.

[48 FR 39836, Sept. 1, 1983, as amended at 48 FR 45774, Oct. 7, 1983; 51 FR 34793, Sept. 30, 1986]

§ 405.1881 Appointment of representative.

A provider or other party may be represented by legal counsel or any other person it appoints to act as its representative at the proceedings, conducted in accordance with §§ 405.1819 and 405.1851.

§ 405.1883 Authority of representative.

A representative appointed by a provider or other party may accept or give on behalf of the provider or other party any request or notice relative to any proceeding before a hearing officer or the Board. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to a request for an intermediary hearing or a Board hearing

made in accordance with §§ 405.1811, 405.1835, or 405.1837 to the same extent as the party he represents. Notice to a provider or other party of any action, determination, or decision, or a request for the production of evidence by a hearing officer or the Board sent to the representative of the provider or other party shall have the same force and effect as if it had been sent to the provider or other party.

§ 405.1885 Reopening a determination or decision.

(a) A determination of an intermediary, a decision by a hearing officer or panel of hearing officers, a decision by the Board, or a decision of the Secretary may be reopened with respect to findings on matters at issue in such determination or decision, by such intermediary officer or panel of hearing officers, Board, or Secretary, as the case may be, either on motion of such intermediary officer or panel of hearing officers, Board, or Secretary, or on the motion of the provider affected by such determination or decision to revise any matter in issue at any such proceedings. Any such request to reopen must be made within 3 years of the date of the notice of the intermediary or Board hearing decision, or where there has been no such decision, any such request to reopen must be made within 3 years of the date of notice of the intermediary determination. No such determination or decision may be reopened after such 3-year period except as provided in paragraphs (d) and (e) of this section.

(b)(1) An intermediary determination or an intermediary hearing decision must be reopened and revised by the intermediary if, within the 3-year period specified in paragraph (a) of this section, CMS—

(i) Provides notice to the intermediary that the intermediary determination or the intermediary hearing decision is inconsistent with the applicable law, regulations, CMS ruling, or CMS general instructions in effect, and as CMS understood those legal provisions, at the time the determination or decision was rendered by the intermediary; and

(ii) Explicitly directs the intermediary to reopen and revise the intermediary determination or the intermediary hearing decision.

(2) A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening an intermediary determination or an intermediary hearing decision under this section.

(3) Notwithstanding paragraph (b)(1)(i) of this section, CMS may direct the intermediary to reopen a particular intermediary determination or intermediary hearing decision in order to implement, for the same intermediary determination or intermediary decision—

(i) A final agency decision under §§ 405.1833, 405.1871(b), 405.1875, or 405.1877(a) of this part;

(ii) A final nonappealable court judgment; or

(iii) An agreement to settle an administrative appeal or a lawsuit.

(c) Jurisdiction for reopening a determination or decision rests exclusively with that administrative body that rendered the last determination or decision.

(d) Notwithstanding the provisions of paragraph (a) of this section, an intermediary determination or hearing decision, a decision of the Board, or a decision of the Secretary shall be reopened and revised at any time if it is established that such determination or decision was procured by fraud or similar fault of any party to the determination or decision.

(e) Notwithstanding an intermediary's discretion to reopen or not reopen an intermediary determination or an intermediary hearing decision under paragraphs (a) and (c) of this section, CMS may direct an intermediary to reopen, or not to reopen, an intermediary determination or an intermediary hearing decision in accordance with paragraphs (a) and (c) of this section.

(f) Paragraphs (a) and (b) of this section apply to determinations on cost reporting periods ending on or after December 31, 1971. (See § 405.1801(c).) However, the 3-year period described shall also apply to determinations with respect to cost reporting periods ending prior to December 31, 1971, but only

if the reopening action was undertaken after May 27, 1972 (the effective date of regulations which, prior to the publication of this subpart R, governed the reopening of such determinations).

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 50110, Aug. 1, 2002]

§405.1887 Notice of reopening.

(a) All parties to any reopening described above shall be given written notice of the reopening. When such reopening results in any revision in the prior decision notice of said revision or revisions will be mailed to the parties with a complete explanation of the basis for the revision or revisions. Notices of reopenings by the Board shall also be sent to the Secretary.

(b) In any such reopening, the parties to the prior decision shall be allowed a reasonable period of time in which to present any additional evidence or argument in support of their position.

§405.1889 Effect of a revision.

Where a revision is made in a determination or decision on the amount of program reimbursement after such determination or decision has been reopened as provided in §405.1885, such revision shall be considered a separate and distinct determination or decision to which the provisions of §§405.1811, 405.1835, 405.1875 and 405.1877 are applicable. (See §405.1801(c) for applicable effective dates.)

Subparts S–T [Reserved]

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§405.2100 Scope of subpart.

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks have in the ESRD program, establish the mechanism by which minimal utilization rates are promulgated and applied, under section 1881(b)(1) of the Act, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in meeting the requirements of section 1881(c) of the Act.

(b) The general objectives of the ESRD program are contained in §405.2101, and general definitions are contained in §405.2102. The provisions of §§405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and membership requirements and restrictions for members of the medical review boards. Sections 405.2120 through 405.2124 discuss the establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130 through 405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160 through 405.2164 discuss specific requirements for facilities which furnish ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

[51 FR 30361, Aug. 26, 1986]

§405.2101 Objectives of the end-stage renal disease (ESRD) program.

The objectives of the end-stage renal disease program are:

(a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;

(b) To encourage proper distribution and effective utlization of ESRD treatment resources while maintaining or improving the quality of care;

(c) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities; and

(d) To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

[43 FR 48950, Oct. 19, 1979]

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

Agreement. A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

Arrangement. A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

Dialysis. A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

End-Stage Renal Disease (ESRD). That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD facility. A facility which is approved to furnish at least one specific ESRD service (see definition of ''ESRD service''). Such facilities are:

(a) *Renal Transplantation Center*. A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.

(b) *Renal dialysis center*. A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(c) *Renal dialysis facility*. A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(d) *Self-dialysis unit*. A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(e) *Special purpose renal dialysis facility*. A renal dialysis facility which is approved under § 405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:

(a) *Transplantation service*. A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.

(b) *Dialysis service*—(1) *Inpatient dialysis*. Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;

(2) *Outpatient dialysis*. Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) *Staff-assisted dialysis*. Dialysis performed by the staff of the center or facility.

(ii) *Self-dialysis*. Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) *Home dialysis*. Dialysis performed by an appropriately trained patient at home.

(c) *Self-dialysis and home dialysis training*. A program that trains ESRD patients to perform self-dialysis or

home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

Furnishes directly. The ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through ''agreements'' or ''arrangements'').

Furnishes on the premises. The ESRD facility furnishes services on its main premises; or on its other premises that are (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility.

Histocompatibility testing. Laboratory test procedures which determine compatibility between a potential organ donor and a potential organ transplant recipient.

Medical care criteria. Predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Medical care norms. Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over a period of time.

Medical care standards. Professionally developed expressions of the range of acceptable variation from a norm or criterion.

Medical care evaluation study (*MCE*). Review of health care services, usually performed retrospectively, in which an indepth assessment of the quality and/or utilization of such services is made.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Network organization. The administrative governing body to the network and liaison to the Federal government.

Organ procurement. The process of acquiring donor kidneys. (See definition of *Organ procurement organization* in §485.302 of this chapter.)

Qualified personnel. Personnel that meet the requirements specified in this paragraph.

(a) *Chief executive officer*. A person who:

(1) Holds at least a baccalaureate degree or its equivalent and has at least 1 year of experience in an ESRD unit; or

(2) Is a registered nurse or physician director as defined in this definition; or

(3) As of September 1, 1976, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.

(b) *Dietitian*. A person who:

(1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or

(2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(c) *Medical record practitioner*. A person who:

(1) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976.

(2) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976, or

(3) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American

Medical Record Association under its requirements in effect June 3, 1976.

(d) *Nurse responsible for nursing service.* A person who is licensed as a registered nurse by the State in which practicing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or

(2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process;

(3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

(e) *Physician-director.* A physician who:

(1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or

(2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program;

(3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(f) *Social worker.* A person who is licensed, if applicable, by the State in which practicing, and

(1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or

(2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition.

(g) *Transplantation surgeon.* A person who:

(1) Is board eligible or board certified in general surgery or urology by a professional board; and

(2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48950, Oct. 19, 1978; 51 FR 30361, Aug. 26, 1986; 53 FR 6547, Mar. 1, 1988; 55 FR 9575, Mar. 14, 1990]

§ 405.2110 Designation of ESRD networks.

CMS designated ESRD networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility.* The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks.* CMS will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in § 405.2101, and compatible with efficient program administration.

[51 FR 30361, Aug. 26, 1986]

§ 405.2111 [Reserved]

§ 405.2112 ESRD network organizations.

CMS will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

(a) Developing network goals for placing patients in settings for self-care and transplantation.

(b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation

and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.

(d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.

(e) Making recommendations to member facilities as needed to achieve network goals.

(f) On or before July 1 of each year, submitting to CMS an annual report that contains the following information:

(1) A statement of the network goals.

(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—

(i) Self-care;

(ii) Transplants; and

(iii) Vocational rehabilitation programs.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care.

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(g) Evaluating and resolving patient grievances.

(h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.

(i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or CMS, using standards of care as specified under paragraph (c) of this section.

(j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

[53 FR 1620, Jan. 21, 1988]

§ 405.2113 Medical review board.

(a) *General*. The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative.

(b) *Restrictions on medical review board members*. (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

§ 405.2114 [Reserved]

§ 405.2120 Minimum utilization rates: general.

Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1)) authorizes the Secretary to limit payment for ESRD care to those facilities that meet the requirements that the Secretary may prescribe, including minimum utilization rates for covered transplantations. The minimum utilization rates, which are explained and specified in §§ 405.2121 through 405.2130, may be changed from time to time in accordance with program experience. Changes will be published as amendments to these regulations.

[55 FR 23440, June 8, 1990]

§ 405.2121 Basis for determining minimum utilization rates.

In developing minimum utilization rates, the Secretary takes into account the performance of ESRD facilities, the

availability of care, the quality of care, and the efficient utilization of equipment and personnel, based on the following evidence:

(a) Information on the geographic distribution of ESRD patients and facilities;

(b) Information on quality of care; and

(c) Information on operational and management efficiency.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

§ 405.2122 Types and duration of classification according to utilization rates.

A renal transplantation center that meets all the other conditions for coverage of ESRD services will be classified according to its utilization rate(s) as follows: Unconditional status, conditional status, exception status, or not eligible for reimbursement for that ESRD service. Such classification will be based on previously reported utilization data (see § 405.2124, except as specified in paragraph (a) of this section), and will be effective until notification of subsequent classification occurs. (See § 405.2123 for reporting requirements; § 405.2124 for method of calculating rates: § 405.2130 for specific standards.)

(a) *Initial classification.* (1) A renal transplantation center that has not previously participated in the ESRD program will be granted conditional status if it submits a written plan, detailing how it will achieve the utilization rates for conditional status by the end of the second calendar year of its operation under the ESRD program, and the rates required for unconditional status by the end of its fourth calendar year of operation.

(2) The renal transplantation center's performance will be evaluated at the end of the first calendar year to ascertain whether it is properly implementing the plan.

(b) *Exception status.* (1) A renal transplantation center that does not meet the minimum utilization rate for unconditional or conditional status may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage under this subpart;

(ii) It is unable to meet the minimum utilization rate because it lacks a sufficient number of patients and is located in an area without a sufficient population base to support a center or facility which would meet the rate; and

(iii) Its absence would adversely affect the achievement of ESRD program objectives.

(2) A hospital that furnishes renal transplantation services primarily to pediatric patients and is approved as a renal dialysis center under this subpart, but does not meet the utilization standards prescribed in § 405.2130(a), may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage as a renal transplantation center;

(ii) The surgery is performed under the direct supervision of a qualified transplantation surgeon (§ 405.2102) who is also performing renal transplantation surgery at an approved renal transplantation center that is primarily oriented to adult nephrology;

(iii) It has an agreement, with the other hospital serviced by the surgeon, for sharing limited resources that are needed for kidney transplantation; and

(iv) There are pediatric patients who need the surgery and who cannot obtain it from any other hospital located within a reasonable distance.

[43 FR 48951, Oct. 19, 1978, as amended at 45 FR 58124, Sept. 2, 1980; 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

§ 405.2123 Reporting of utilization rates for classification.

Each hospital furnishing renal transplantation services must submit an annual report to CMS on its utilization rates. The report must include both the number of transplants performed during the most recent year of operation and the number performed during each of the preceding 2 calendar years.

[55 FR 23441, June 8, 1990]

§405.2124 Calculation of utilization rates for comparison with minimal utilization rate(s) and notification of status.

For purposes of classification the Secretary will use either the utilization rate for the preceding 12 months or the average utilization rate of the preceding 2 calendar years, whichever is higher. The Secretary will inform each ESRD facility and the network coordinating council of the network area in which the ESRD facility is located of the results of this classification.

§405.2130 Condition: Minimum utilization rates.

Unless a renal transplantation center is granted an exception under §405.2122(b), the center must meet the following minimum utilization rate(s) for unconditional or conditional status:

(a) Unconditional status: 15 or more transplants performed annually.

(b) Conditional status: 7 to 14 transplants performed annually.

[55 FR 23441, June 8, 1990]

§405.2131 Condition: Provider status: Renal transplantation center or renal dialysis center.

A renal transplantation center or a renal dialysis center (§405.2102(e) (1) or (2)) operated by a hospital may qualify for approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program.

§405.2132 [Reserved]

§405.2133 Condition: Furnishing data and information for ESRD program administration.

The ESRD facility, laboratory performing histocompatibility testing, and organ procurement organization furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR parts 5, 5b, and part 401 of this chapter).

[53 FR 6548, Mar. 1, 1988]

§405.2134 Condition: Participation in network activities.

Each facility must participate in network activities and pursue network goals.

[51 FR 30362, Aug. 26, 1986]

§405.2135 Condition: Compliance with Federal, State and local laws and regulations.

The ESRD facility is in compliance with applicable Federal, State and local laws, and regulations.

(a) *Standard: licensure.* Where State or applicable local law provides for the licensing of ESRD facilities, the facility is:

(1) Licensed pursuant to such law; or

(2) Approved by the agency of such State or locality responsible for such licensing as meeting the standards established for such licensing.

(b) *Standard: licensure or registration of personnel.* Each staff member is currently licensed or registered in accordance with applicable law.

(c) *Standard: conformity with other laws.* The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.

§405.2136 Condition: Governing body and management.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer

who is responsible for the overall management of the facility.

(a) *Standard: disclosure of ownership.* The ESRD facility supplies full and complete information to the State survey agency (§ 405.1902(a)) as to the identity of:

(1) Each person who has any direct or indirect ownership interest of 10 per centum or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility;

(2) Each officer and director of the corporation, if the facility is organized as a corporation; and

(3) Each partner, if the facility is organized as a partnership; and promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.

(b) *Standard: Operational objectives.* The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary. If the ESRD facility is engaged in the practice of hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect to reuse, to assure that recommended standards and conditions are being followed, and requires that patients be informed of the policies and procedures.

(1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public.

(2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that may be performed, is readily available upon request to all concerned.

(3) Admission criteria that insure equitable access to services are adopted by the facility and are readily available to the public. Access to the self-dialysis unit is available only to patients for whom the facility maintains patient care plans (see § 405.2137).

(4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.

(c) *Standard: chief executive officer.* The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.

(1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.

(2) The chief executive officer serves on a full-time or part-time basis, in accordance with the scope of the facility's operations and administrative needs, and devotes sufficient time to the conduct of such responsibilities.

(3) The responsibilities of the chief executive officer include but are not limited to:

(i) Implementing the policies of the facility and coordinating the provision

of services, in accordance with delegations by the governing body.

(ii) Organizing and coordinating the administrative functions of the facility, redelegating duties as authorized, and establishing formal means of accountability for those involved in patient care.

(iii) Authorizing expenditures in accordance with established policies and procedures.

(iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations.

(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary.

(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to approval by the governing body of such agreements or contracts.

(vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation.

(viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.

(d) *Standard: personnel policies and procedures.* The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and promote good personnel practices. These policies and procedures ensure that:

(1) All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.

(2) A safe and sanitary environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.

(3) If the services of trainees are utilized in providing ESRD services, such trainees are under the direct supervision of qualified professional personnel.

(4) Complete personnel records are maintained on all personnel. These include health status reports, resumes of training and experience, and current job descriptions that reflect the employees' responsibilities and work assignments.

(5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances.

(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover initial orientation, and continuing in-service training, including procedures for infection control. Records are maintained showing the content of training sessions and the attendance at such sessions.

(7) Personnel manuals are maintained, periodically updated, and made available to all personnel involved in patient care.

(e) *Standard: use of outside resources.* If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service.

The chief executive officer when utilizing outside resource, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

(f) *Standard: patient care policies*. The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients. The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out. These policies are developed by the physician responsible for supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care.

(1) The patient care policies cover the following:

(i) Scope of services provided by the facility (either directly or under arrangement).

(ii) Admission and discharge policies (in relation to both in-facility care and home care).

(iii) Medical supervision and physician services.

(iv) Patient long term programs, patient care plans and methods of implementation.

(v) Care of patients in medical and other emergencies.

(vi) Pharmaceutical services.

(vii) Medical records (including those maintained in the ESRD facility and in the patients' homes, to ensure continuity of care).

(viii) Administrative records.

(ix) Use and maintenance of the physical plant and equipment.

(x) Consultant qualifications, functions, and responsibilities.

(xi) The provision of home dialysis support services, if offered (see § 405.2163(e)).

(2) The physician-director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated by a physican director to (or, in the case of a self-dialysis unit, to another licensed health practitioner) a registered nurse, the physican-director provides medical guidance in such matters.

(3) The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their nonworking hours.

(4) The governing body adopts policies to ensure there is evaluation of the progress each patient is making toward the goals stated in the patient's long term program and patient's care plan (see § 405.2137(a)). Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.

(g) *Standard: medical supervision and emergency coverage*. The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations.

(1) The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge. Such plans are made with input from other professional personnel involved in the care of the patient.

(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

(h) *Standard: medical staff*. The governing body of the ESRD facility designates a qualified physician (see

§405.2102) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§405.2137 Condition: Patient long-term program and patient care plan.

Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer.

(a) *Standard: patient long-term program.* There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.

(1) The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see §405.2161(b)(1) and §405.2170(a)).

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.

(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.

(b) *Standard: patient care plan.* There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see §405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients ongoing needs.

(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

(6) For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions

for visits to the home by qualified facility personnel to the extent appropriate. (See § 405.2163(e).)

(7) Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient, who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following:

(i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.

(ii) Review of medications to ensure adequate provision of supplemental iron.

(iii) Ongoing evaluations of hematocrit and iron stores.

(iv) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume.

(v) A method for physician followup on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results.

(vi) Training of the patient to identify the signs and symptoms of hypotension and hypertension.

(vii) The decrease or discontinuance of EPO if hypertension is uncontrollable.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994]

§ 405.2138 Condition: Patients' rights and responsibilities.

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and subpart Q of 20 CFR part 404), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following:

(a) *Standard: informed patients.* All patients in the facility:

(1) Are fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities;

(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records);

(4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

(5) Are fully informed regarding their suitability for transplantation and home dialysis.

(b) *Standard: participation in planning.* All patients treated in the facility:

(1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.

(c) *Standard: respect and dignity.* All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers.

(d) *Standard: confidentiality.* All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

(e) *Standard: grievance mechanism.* All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes

in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§405.2139 Condition: Medical records.

The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) *Standard: medical record*. Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see §405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in §405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis.

(b) *Standard: protection of medical record information*. The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

(c) *Standard: medical records supervisor*. A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

(d) *Standard: Completion of medical records and centralization of clinical information*. Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

(e) *Standard: retention and preservation of records*. Medical records are retained for a period of time not less than that determined by the State statute governing records retention or

statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

(f) *Standard: location and facilities.* The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

(g) *Standard: transfer of medical information.* The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 52 FR 36934, Oct. 2, 1987]

§ 405.2140 Condition: Physical environment.

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

(a) *Standard: building and equipment.* The physical structure in which ESRD services are furnished is constructed, equipped, and maintained to insure the safety of patients, staff, and the public.

(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.

(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients or personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

(3) The areas used by patients are maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building.

(4) [Reserved]

(5)(i) The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in ''Hemodialysis Systems,'' second edition, which is incorporated by reference.

(ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2, Maximum Level of Chemical Contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5.

(iii) Incorporation by reference of the AAMI's ''Hemodialysis Systems,'' second edition, 1992, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] If any changes in ''Hemodialysis Systems,'' second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(b) *Standard: favorable environment for patients.* The facility is maintained and equipped to provide a functional sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation and

[1] The publication entitled ''Hemodialysis Systems,'' second edition, 1992, is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244–1850 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

storage of reused items which conform to requirements for reuse in §405.2150.

(2) Treatment areas are designed and equipped to provide adequate and safe dialysis therapy, as well as privacy and comfort for patients. The space for treating each patient is sufficient to accomodate medically needed emergency equipment and staff and to ensure that such equipment and staff can reach the patient in an emergency. There is sufficient space in units for safe storage of self-dialysis supplies.

(3) There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made.

(4) Heating and ventilation systems are capable of maintaining adequate and comfortable temperatures.

(5) Each ESRD facility utilizing a central-batch delivery system provides, either on the premises or through affiliation agreement or arrangement (see §405.2160) sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.

(c) *Standard contamination prevention.* The facility employs appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems. Waste storage and disposal are carried out in accordance with applicable local laws and accepted public health procedures. The written patient care policies (see §405.2136(f)(1)) specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention. Where dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items, conform to requirements for reuse in §405.2150.

(d) *Standard: emergency preparedness.* Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations.

(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.

(2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specified role in case of an emergency.

(3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

(4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

(5) Patients are trained to handle medical and nonmedical emergencies. Patients must be fully informed regarding what to do, where to go, and whom to contact if a medical or nonmedical emergency occurs.

(Secs. 1102, 1871, 1881(b), Social Security Act; 42 U.S.C. 1302, 1395hh, 1395rr(b))

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 45 FR 24839, Apr. 10, 1980; 52 FR 36934, Oct. 2, 1987; 60 FR 48043, Sept. 18, 1995; 69 FR 18803, Apr. 9, 2004]

§405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies.

An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this section. Failure to meet any of paragraphs (a) through (c) of this section constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.

(a) *Standard: Hemodialyzers.* If the ESRD facility reuses hemodialyzers, it conforms to the following:

(1) *Reuse guidelines.* Voluntary guidelines adopted by the AAMI (''Reuse of Hemodialyzers,'' second edition). Incorporation by reference of the AAMI's ''Reuse of Hemodialyzers,'' second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] If any changes in ''Reuse of Hemodialyzers,'' second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(2) *Procedure for chemical germicides.* To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.

(3) *Surveillance of patient reactions.* In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility—

(i) Takes appropriate blood cultures at the time of a febrile response in a patient; and

(ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.

(b) *Standard: Transducer filters.* To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.

(c) *Standard: Bloodlines.* If the ESRD facility reuses bloodlines, it must—

(1) Limit the reuse of bloodlines to the same patient;

(2) Not reuse bloodlines labeled for ''single use only'';

(3) Reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the Food and Drug Administration (FDA) pursuant to the premarket notification (section 510(k)) provision of the Food, Drug, and Cosmetic Act; and

(4) Follow the FDA-accepted manufacturer's protocol for reuse of that bloodline.

[52 FR 36935, Oct. 2, 1987, as amended at 55 FR 18335, May 2, 1990; 60 FR 48044, Sept. 18, 1995; 69 FR 18803, Apr. 9, 2004]

§ 405.2160 Condition: Affiliation agreement or arrangement.

(a) A renal dialysis facility and a renal dialysis center (see § 405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services.

(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:

(1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and

(3) Security and accountability for patients' personal effects are assured.

[1] The publication entitled ''Reuse of Hemodialyzers,'' second edition, 1993, is available for inspection at the CMS Information Resources Center, 7500 Security Boulevard, Baltimore, MD 21244–1850 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

§ 405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.

Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) *Standard: qualifications.* The director of a dialysis facility is a qualified physician-director. (See § 405.2102.)

(b) *Standard: responsibilities.* The responsibilities of the physician-director include but are not limited to the following:

(1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

(2) Assuring adequate training of nurses and technicians in dialysis techniques;

(3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and

(5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.

Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.

(a) *Standard: Registered nurse.* The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See § 405.2102.)

(b) *Standard: On-duty personnel.* Whenever patients are undergoing dialysis:

(1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care;

(2) An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and

(3) An adequate number of personnel are readily available to meet medical and nonmedical needs.

(c) *Standard: Self-care dialysis training personnel.* If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see § 405.2102.)

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

The facility must provide dialysis services, as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient.

(a) *Standard: Outpatient dialysis services*—(1) *Staff-assisted dialysis services.* The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.

(2) *Self-dialysis services.* If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in

accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter. If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

(c) *Standard: Social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(d) *Standard: Dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(e) *Standard: Self-dialysis support services.* The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services:

(1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;

(2) Consultation for the patient with a qualified social worker and a qualified dietitian;

(3) A recordkeeping system which assures continuity of care;

(4) Installation and maintenance of equipment;

(5) Testing and appropriate treatment of the water; and

(6) Ordering of supplies on an ongoing basis.

(f) *Standard: Participation in recipient registry.* The dialysis facility or center participates in a patient registry program with an OPO designated or redesignated under part 486, subpart G of this chapter, for patients who are awaiting cadaveric donor transplantation.

(g) *Use of EPO at home: Patient selection.* The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

(1) *Pre-selection monitoring.* The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

(2) *Conditions the patient must meet.* The assessment must find that the patient meets the following conditions:

(i) On or after July 1, 1991, is a home dialysis patient or, on or after January 1, 1994, is a dialysis patient;

(ii) Has a hematocrit (or comparable hemoglobin level) that is as follows:

(A) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. (Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.)

(B) For a patient who has been receiving EPO from the facility or the physician, between 30 and 33 percent.

(iii) Is under the care of—

(A) A physician who is responsible for all dialysis-related services and who

prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and

(B) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

(3) *Conditions the patient or the patient's caregiver must meet.* The assessment must find that the patient or a caregiver who assists the patient in performing self-dialysis meets the following conditions:

(i) Is trained by the facility to inject EPO and is capable of carrying out the procedure.

(ii) Is capable of reading and understanding the drug labeling.

(iii) Is trained in, and capable of observing, aseptic techniques.

(4) *Care and storage of drug.* The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

(h) *Use of EPO at home: Responsibilities of the physician or the dialysis facility.* The patient's physician or dialysis facility must—

(1) Develop a protocol that follows the drug label instructions;

(2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and

(3) Through the amounts prescribed, ensure that the drug ''on hand'' at any time does not exceed a 2-month supply.

[43 FR 48953, Oct. 19, 1978, as amended at 51 FR 30362, Aug. 26, 1986; 57 FR 7134, Feb. 28, 1992; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994; 59 FR 46513, Sept. 8, 1994; 61 FR 19743, May 2, 1996]

§ 405.2164 Conditions for coverage of special purpose renal dialysis facilities.

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§ 405.2130 through 405.2164, with the exception of §§ 405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's long-term program and patient care plan required under § 405.2137.

(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

[48 FR 21283, May 11, 1983, as amended at 51 FR 30362, Aug. 26, 1986]

§ 405.2170 Condition: Director of a renal transplantation center.

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§ 405.2102) or a qualified physician-director (§ 405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

(a) Participating in the selection of a suitable treatment modality for each patient.

(b) Assuring adequate training, of nurses in the care of transplant patients.

(c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

(d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 59 FR 46514, Sept. 8, 1994]

§ 405.2171 Condition: Minimal service requirements for a renal transplantation center.

Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by CMS as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff;

if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator and medical staff, respectively. Patients are accepted for transplantation only on the order of a physician and their care continues under the supervision of a physician.

(a) *Standard: participation in recipient registry*. The renal transplantation center participates in a patient registry program with an OPO certified or recertified under part 485, subpart D of this chapter for patients who are awaiting cadaveric donor transplantation.

(b) *Standard: social services*. Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(c) *Standard: dietetic services*. Each patient is evaluated as to his nutritional needs by the attending physician and a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(d) *Standard: Laboratory services:* (1) The renal transplantation center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified in accordance with part 493 of this chapter.

(2) Laboratory services for crossmatching of recipient serum and donor lymphocytes for pre-formed antibodies by an acceptable technique are available on a 24-hour emergency basis.

(e) *Standard: Organ procurement*. A renal transplantation center using the services of an organ procurement organization designated or redesignated under part 485, subpart D of this chapter to obtain donor organs has a written agreement covering these services. The renal transplantation center agrees to notify CMS in writing within 30 days of the termination of the agreement.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 53 FR 6548, Mar. 1, 1988; 57 FR 7134, Feb. 28, 1992; 59 FR 46514, Sept. 8, 1994]

§ 405.2180 Termination of Medicare coverage.

(a) Except as provided in § 405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this subpart U will result in termination of Medicare coverage of the services furnished by that supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required by § 405.2134, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in this subpart, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

[53 FR 36277, Sept. 19, 1988]

§ 405.2181 Alternative sanctions.

(a) *Basis for application of alternative sanctions*. CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass its geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of sanction.* An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

[53 FR 36277, Sept. 19, 1988]

§405.2182 Notice of sanction and appeal rights: Termination of coverage.

(a) *Notice of sanction.* CMS gives the supplier and the general public notice of sanction and of the effective date of the sanction. The effective date of the sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

[53 FR 36277, Sept. 19, 1988]

§405.2184 Notice of appeal rights: Alternative sanctions.

If CMS proposes to apply a sanction specified in §405.2181(b), the following rules apply:

(a) CMS gives the facility notice of the proposed sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the sanction, with a written notice that specifies the effective date and the reasons for the sanction.

[53 FR 36277, Sept. 19, 1988]

Subparts V–W [Reserved]

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

§405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act: Section 1833 sets forth the amounts of payment for supplementary medical insurance services. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program.

[60 FR 63176, Dec. 8, 1995]

§405.2401 Scope and definitions.

(a) *Scope.* This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise:

Act means the Social Security Act.

Allowable costs means costs that are incurred by a clinic or center and are reasonable in amount and proper and necessary for the efficient delivery of rural health clinic and Federally qualified health center services.

Beneficiary means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

Coinsurance means that portion of the clinic's charge for covered services for which the beneficiary is liable in addition to the deductible.

Carrier means an organization that has a contract with the Secretary to administer the benefits covered by this subpart.

Covered services means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

Deductible means:

(1) The first $100 of expenses incurred by the beneficiary during any calendar year for items and services covered under Part B of title XVIII; and

(2) The expenses incurred for the first 3 pints of blood or 3 units of packed red blood cells furnished to a beneficiary during any calendar year. (See §§ 410.160 and 410.161 of this chapter for greater detail.)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under §§ 405.2434 and—

(1) Is receiving a grant under section 329, 330, or 340 of the Public Health Service Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 329, 330 or 340 of the Public Health Service Act;

(2) Based on the recommendation of the PHS, is determined by CMS to meet the requirements for receiving such a grant;

(3) Was treated by CMS, for purposes of part B, as a comprehensive federally funded health center (FFHC) as of January 1, 1990; or

(4) Is an outpatient health program or facility operated by a tribe or tribal organizations under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

CMS stands for Centers for Medicare & Medicaid Services.

Intermittent nursing care means a medically predictable need for nursing care from time to time, but usually not less frequently than once every 60 days.

Nurse-midwife means a registered professional nurse who meets the following requirements:

(1) Is currently licensed to practice in the State as a registered professional nurse.

(2) Is legally authorized under State law or regulations to practice as a nurse-midwife.

(3) Except as provided in paragraph (b)(10)(iv) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.

(4) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:

(i) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives.

(ii) Has satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives.

(iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

Nurse practitioner and *physician assistant* means individuals who meet the applicable education, training experience and other requirements of § 491.2 of this chapter.

Part-time nursing care means nursing care that is required on less than a

full-time basis, that is, less than 8 hours a day or 40 hours a week.

Physician means the following:

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the function is performed.

(2) Within limitations as to the specific services furnished, a doctor of dentistry or dental or oral surgery, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor. (See section 1861(r) of the Act for specific limitations.)

(3) A resident (including residents as defined in § 415.152 of this chapter who meet the requirements in § 415.206(b) of this chapter for payment under the physician fee schedule).

Reporting period means a period of 12 consecutive months specified by the intermediary as the period for which a clinic or center must report its costs and utilization. The first and last reporting periods may be less than 12 months.

Rural health clinic (RHC) means an entity that:

(1) Meets the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval.

(2) Has filed an agreement with CMS that meets the basic requirements described in § 405.2402 to provide RHC services under Medicare.

(3) Does not share space, staff, supplies, records, and other resources during RHC hours of operation with a private Medicare or Medicaid practice operated by the same physicians and nonphysician practitioners working for the RHC. Operation of a multipurpose clinic with other types of health providers or suppliers is permissible subject to the provisions in paragraph (4) of this definition.

(4) Appropriately allocates and excludes from the RHC cost report the net non-RHC costs if it operates at a multipurpose location that involves the sharing of common space, medical support staff, or other physical resources with other health care providers or suppliers.

Secretary means the Secretary of Health and Human Services or his delegate.

Visiting nurse services means part-time or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered nurse or licensed practical nurse to a homebound patient.

(Secs. 1102, 1833, 1861(aa), 1871, 1902(a)(13), Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485 (42 U.S.C. 1302, 1395*l*, 1395hh, 1395x(aa), and 1396(a)(13))

[43 FR 8261, Mar. 1, 1978, as amended at 43 FR 30526, July 14, 1978; 47 FR 21049, May 17, 1982; 47 FR 23448, May 28, 1982; 51 FR 41351, Nov. 14, 1986; 57 FR 24975, June 12, 1992; 59 FR 26958, May 25, 1994; 60 FR 63176, Dec. 8, 1995; 61 FR 14657, Apr. 3, 1996; 69 FR 74815, Dec. 24, 2003]

§ 405.2402 Basic requirements.

(a) *Certification by the State survey agency*. The rural health clinic must be certified in accordance with part 491 of this chapter.

(b) *Acceptance of the clinic as qualified to furnish rural health clinic services*. If the Secretary, after reviewing the survey agency recommendation and other evidence relating to the qualifications of the rural health clinic, determines that it meets the requirements of this subpart and of part 491 of this chapter, he will send the clinic:

(1) Written notice of the determination; and

(2) Two copies of the agreement to be filed as required by section 1861(aa)(1) of the Act.

(c) *Filing of agreement by the rural health clinic*. If the rural health clinic wishes to participate in the program, it must:

(1) Have both copies of the agreement signed by an authorized representative; and

(2) File them with the Secretary.

(d) *Acceptance by the Secretary*. If the Secretary accepts the agreement filed by the rural health clinic, he will return to the clinic one copy of the agreement, with a notice of acceptance specifying the effective date.

(e) *Duration of agreement*. The agreement shall be for a term of one year and may be renewed annually by mutual consent of the Secretary and the rural health clinic.

(f) *Appeal rights*. If the Secretary does not certify a rural health clinic, or refuses to enter into or renew an agreement, the facility is entitled to a hearing in accordance with part 498 of this chapter.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987]

§ 405.2403 Content and terms of the agreement with the Secretary.

(a) Under the agreement, the rural health clinic agrees to the following:

(1) *Maintaining compliance with conditions*. The clinic agrees to maintain compliance with the conditions set forth in part 491 of this chapter and to report promptly to CMS any failure to do so.

(2) *Charges to beneficiaries*. The clinic agrees not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part (or for which the beneficiary would have been entitled if the rural health clinic had filed a request for payment in accordance with § 410.165 of this chapter), except for any deductible or coinsurance amounts for which the beneficiary is liable under § 405.2410.

(3) *Refunds to beneficiaries*. (i) The clinic agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(ii) As used in this section, *money incorrectly collected* means sums collected in excess of the amount for which the beneficiary was liable under § 405.2410. It includes amounts collected at a time when the beneficiary was believed not to be entitled to Medicare benefits but:

(A) The beneficiary is later determined to have been entitled to Medicare benefits; and

(B) The beneficiary's entitlement period falls within the time the rural health clinic's agreement with the Secretary is in effect.

(4) *Beneficiary treatment*. (i) The clinic agrees to accept beneficiaries for care and treatment; and

(ii) The clinic agrees not to impose any limitations on the acceptance of beneficiaries for care and treatment that it does not impose on all other persons.

(b) *Additional provisions*. The agreement may contain any additional provisions that the Secretary finds necessary or desirable for the efficient and effective administration of the Medicare program.

[43 FR 8261, Mar. 1, 1978, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.2404 Terminations of agreements.

(a) *Termination by rural health clinic*. (1) *Notice to Secretary*. If the clinic wishes to terminate its agreement it shall file with the Secretary a written notice stating the intended effective date of termination.

(2) *Action by the Secretary*. (i) The Secretary may approve the date proposed by the clinic, or set a different date no later than 6 months after the date of the clinic's notice.

(ii) The Secretary may approve a date which is less than 6 months after the date of notice if he determines that termination on that date would not:

(A) Unduly disrupt the furnishing of services to the community serviced by the clinic; or

(B) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Cessation of business*. If a clinic ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the clinic, effective on the last day of business.

(b) *Termination by the Secretary*. (1) *Cause for termination*. The Secretary may terminate an agreement if he determines that the rural health clinic:

(i) No longer meets the conditions for certification under part 491 of this chapter; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act; or

(iii) Has undergone a change of ownership.

(2) *Notice of termination*. The Secretary will give notice of termination to the rural health clinic at least 15 days before the effective date stated in the notice.

(3) *Appeal by the rural health clinic.* A rural health clinic may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment will not be available for rural health clinic services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination shall be given to the public, through publication in local newspapers:

(1) By the clinic, after the Secretary has approved or set a termination date; or

(2) By the Secretary, when he has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by the Secretary.* When an agreement with a rural health clinic is terminated by the Secretary, the rural health clinic may not file another agreement to participate in the Medicare program unless the Secretary:

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987]

§405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for RHC services begins only after the beneficiary has incurred the deductible. Medicare applies the Medicare Part B deductible as follows:

(i) If the deductible is fully met by the beneficiary before the RHC visit, Medicare pays 80 percent of the all-inclusive rate.

(ii) If the deductible is not fully met by the beneficiary before the visit and the amount of the RHC's reasonable customary charge for the service that is applied to the deductible is—

(A) Less than the all-inclusive rate, the amount applied to the deductible is subtracted from the all-inclusive rate and 80 percent of the remainder, if any, is paid to the RHC; or

(B) Equal to or exceeds the all-inclusive rate, no payment is made to the RHC.

(2) Medicare payment for FQHC services is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* (1) The beneficiary is responsible for the coinsurance amount that cannot exceed 20 percent of the clinic's reasonable customary charge for the covered service.

(2) The beneficiary's deductible and coinsurance liability for any one service furnished by the RHC may not exceed a reasonable amount customarily charged by the RHC for that particular service.

(3) For any one service furnished by an FQHC, the coinsurance liability may not exceed 20 percent of reasonable amount customarily charged by the FQHC for that particular service.

[69 FR 74815, Dec. 24, 2003]

§405.2411 Scope of benefits.

(a) Rural health clinic services reimbursable under this subpart are:

(1) The physicians' services specified in §405.2412;

(2) Services and supplies furnished as an incident to a physician's professional service;

(3) The nurse practitioner or physician assistant services specified in §405.2414;

(4) Services and supplies furnished as an incident to a nurse practitioner's or physician assistant's services; and

(5) Visiting nurse services.

(b) Rural health clinic services are reimbursable when furnished to a patient at the clinic, at a hospital or other medical facility, or at the patient's place of residence.

§405.2412 Physicians' services.

(a) Physicians' services are professional services that are performed by a physician at the clinic or are performed away from the clinic by a physician whose agreement with the clinic provides that he or she will be paid by the clinic for such services.

§405.2413 Services and supplies incident to a physician's services.

(a) Services and supplies incident to a physician's professional service are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;

(3) Furnished as an incidental, although integral, part of a physician's professional services;

(4) Furnished under the direct, personal supervision of a physician; and

(5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

§ 405.2414 Nurse practitioner and physician assistant services.

(a) Professional services are reimbursable under this subpart if:

(1) Furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner who is employed by, or receives compensation from, the rural health clinic;

(2) Furnished under the medical supervision of a physician;

(3) Furnished in accordance with any medical orders for the care and treatment of a patient prepared by a physician;

(4) They are of a type which the nurse practitioner, physician assistant, nurse midwife or specialized nurse practitioner who furnished the service is legally permitted to perform by the State in which the service is rendered; and

(5) They would be covered if furnished by a physician.

(b) The physician supervision requirement is met if the conditions specified in § 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of nurse practitioners, physician assistants, nurse midwives or specialized nurse practitioners are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

§ 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.

(a) Services and supplies incident to a nurse practitioner's or physician assistant's services are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner;

(4) Furnished under the direct, personal supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner or a physician; and

(5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) The direct personal supervision requirement is met in the case of a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to supervise such services under the written policies governing the rural health clinic.

(c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

§ 405.2416 Visiting nurse services.

(a) Visiting nurse services are covered if:

(1) The rural health clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies;

(2) The services are rendered to a homebound individual;

(3) The services are furnished by a registered nurse, licensed practical nurse, or licensed vocational nurse who is employed by, or receives compensation for the services from the clinic; and

(4) The services are furnished under a written plan of treatment that is:

(i) Established and reviewed at least every 60 days by a supervising physician of the rural health clinic or established by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner and reviewed at least every 60 days by a supervising physician; and

(ii) Signed by the nurse practitioner, physician assistant, nurse midwife,

specialized nurse practitioner, or the supervising physician of the clinic.

(b) The nursing care covered by this section includes:

(1) Services that must be performed by a registered nurse, licensed practical nurse, or licensed vocational nurse if the safety of the patient is to be assured and the medically desired results achieved; and

(2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications.

(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.

(d) For purposes of this section, *homebound* means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, ''place of residence'' does not include a hospital or long term care facility.

§ 405.2417 Visiting nurse services: Determination of shortage of agencies.

A shortage of home health agencies exists if the Secretary determines that the rural health clinic:

(a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the rural health clinic;

(b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency; or

(c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.

FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24978, June 12, 1992, unless otherwise noted.

§ 405.2430 Basic requirements.

(a) *Filing procedures.* (1) In response to a request from an entity that wishes to participate in the Medicare program, CMS enters into an agreement with an entity when—

(i) PHS recommends that the entity qualifies as a Federally qualified health center;

(ii) The Federally qualified health center assures CMS that it meets the Federally qualified health center requirements specified in this subpart and part 491, as described in § 405.2434(a); and

(iii) The FQHC terminates other provider agreements, unless the FQHC assures CMS that it is not using the same space, staff and resources simultaneously as a physician's office or another type of provider or supplier. A corporate entity may own other provider types as long as the provider types are distinct from the FQHC.

(2) CMS sends the entity a written notice of the disposition of the request.

(3) When the requirement of paragraph (a)(1) of this section is satisfied, CMS sends the entity two copies of the agreement. The entity must sign and return both copies of the agreement to CMS.

(4) If CMS accepts the agreement filed by the Federally qualified health center, CMS returns to the center one copy of the agreement with the notice of acceptance specifying the effective date (see § 489.11), as determined under § 405.2434.

(b) *Recommendations by PHS about Federally qualified health centers.* (1) An entity must—

(i) Meet the applicable requirements of the PHS Act, as specified in § 405.2401(b); and

(ii) Be recommended by PHS to CMS as a Federally qualified health center.

(2) The PHS notifies CMS of entities that meet the requirements specified in § 405.2401(b).

(c) *Provider-based and freestanding Federally qualified health centers.* The requirements and benefits under Medicare for provider-based or freestanding Federally qualified health centers are the same, except that payment methodologies differ, as described in § 405.2462.

(d) *Appeals.* An entity is entitled to a hearing in accordance with part 498 of this chapter when CMS fails to enter into an agreement with the entity.

[57 FR 24978, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2434 Content and terms of the agreement.

Under the agreement, the Federally qualified health center must agree to the following:

(a) *Maintain compliance with the requirements.* (1) The Federally qualified health center must agree to maintain compliance with the Federally qualified health center requirements set forth in this subpart and part 491, except that the provisions of § 491.3 do not apply.

(2) Centers must promptly report to CMS any changes that result in noncompliance with any of these requirements.

(b) *Effective date of agreement.* (1) Except as specified in paragraph (b)(2) of this section, the effective date of the agreement is the date CMS accepts the signed agreement, which assures that all Federal requirements are met.

(2) For facilities that met all requirements on October 1, 1991, the effective date of the agreement can be October 1, 1991.

(c) *Charges to beneficiaries.* (1) The beneficiary is responsible for payment of a coinsurance amount which is 20 percent of the amount of Part B payment made to the Federally qualified health center for the covered services. There is no coinsurance for a second or third opinion obtained in accordance with section 1164 of the Act or for pneumococcal vaccine and its administration.

(2) The beneficiary is responsible for blood deductible expenses, as specified in § 410.161.

(3) The Federally qualified health center agrees not to charge the beneficiary (or any other person acting on behalf of a beneficiary) for any Federally qualified health center services for which the beneficiary is entitled to have payment made on his or her behalf by the Medicare program (or for which the beneficiary would have been entitled if the Federally qualified health center had filed a request for payment in accordance with § 410.165 of this chapter), except for coinsurance amounts.

(4) The Federally qualified health center may charge the beneficiary for items and services that are not Federally qualified health center services. However, if the item or service is covered under Part B of Medicare, and the Federally qualified health center agrees to receive Part B payment under the assignment method, the Federally qualified health center may not charge the beneficiary more than 20 percent of the Part B payment.

(d) *Refunds to beneficiaries.* (1) The Federally qualified health center must agree to refund as promptly as possible any money incorrectly collected from Medicare beneficiaries or from someone on their behalf.

(2) As used in this section, ''money incorrectly collected'' means any amount for covered services that is greater than the amount for which the beneficiary was liable because of the coinsurance requirements specified in part 410, subpart E.

(3) Amounts also are considered incorrectly collected if the Federally qualified health center believed the beneficiary was not entitled to Medicare benefits but—

(i) The beneficiary was later determined to have been so entitled;

(ii) The beneficiary's entitlement period fell within the time the Federally qualified health center's agreement with CMS was in effect; and

(iii) The amounts exceed the beneficiary's coinsurance liability.

(e) *Treatment of beneficiaries.* (1) The Federally qualified health center must agree to accept Medicare beneficiaries for care and treatment.

(2) The Federally qualified health center may not impose any limitations with respect to care and treatment of Medicare beneficiaries that it does not also impose upon all other persons seeking care and treatment from the Federally qualified health center. Failure to comply with this requirement is a cause for termination of the Federally qualified health center's agreement with CMS in accordance with § 405.2436(d).

(3) If the Federally qualified health center does not furnish treatment for

certain illnesses and conditions to patients who are not Medicare beneficiaries, it need not furnish such treatment to Medicare beneficiaries.

§ 405.2436 Termination of agreement.

(a) *Termination by Federally qualified health center*. The Federally qualified health center may terminate its agreement by—

(1) Filing with CMS a written notice stating its intention to terminate the agreement; and

(2) Notifying CMS of the date on which the Federally qualified health center requests that the termination take effect.

(b) *Effective date*. (1) Upon receiving a Federally qualified health center's notice of intention to terminate the agreement, CMS will set a date upon which the termination takes effect. This effective date may be—

(i) The date proposed by the Federally qualified health center in its notice of intention to terminate, if that date is acceptable to CMS; or

(ii) Except as specified in paragraph (2) of this section, a date set by CMS, which is no later than 6 months after the date CMS receives the Federally qualified health center's notice of intention to terminate.

(2) The effective date of termination may be less than 6 months following CMS's receipt of the Federally qualified health center's notice of intention to terminate if CMS determines that termination on such a date would not—

(i) Unduly disrupt the furnishing of Federally qualified health center services to the community; or

(ii) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) The termination is effective at the end of the last day of business as a Federally qualified health center.

(c) *Termination by CMS*. (1) CMS may terminate an agreement with a Federally qualified health center if it finds that the Federally qualified health center—

(i) No longer meets the requirements specified in this subpart; or

(ii) Is not in substantial compliance with—

(A) The provisions of the agreement; or

(B) The requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act.

(2) *Notice by CMS*. CMS will notify the Federally qualified health center in writing of its intention to terminate an agreement at least 15 days before the effective date stated in the written notice.

(3) *Appeal*. A Federally qualified health center may appeal CMS's decision to terminate the agreement in accordance with part 498 of this chapter.

(d) *Effect of termination*. When a Federally qualified health center's agreement is terminated whether by the Federally qualified health center or CMS, payment will not be available for Federally qualified health center services furnished on or after the effective date of termination.

§ 405.2440 Conditions for reinstatement after termination by CMS.

When CMS has terminated an agreement with a Federally qualified health center, CMS will not enter into another agreement with the Federally qualified health center to participate in the Medicare program unless CMS—

(a) Finds that the reason for the termination no longer exists; and

(b) Is assured that the reason for the termination of the prior agreement will not recur.

§ 405.2442 Notice to the public.

(a) When the Federally qualified health center voluntarily terminates the agreement and an effective date is set for the termination, the Federally qualified health center must notify the public prior to a prospective effective date or on the actual day that business ceases, if no prospective date of termination has been set, through publication in at least one newspaper in general circulation in the area serviced by the Federally qualified health center of the—

(1) Effective date of termination of the provision of services; and

(2) Effect of termination of the agreement.

(b) When CMS terminates the agreement, CMS will notify the public through publication in at least one newspaper in general circulation in the

Federally qualified health center's service area.

§ 405.2444 Change of ownership.

(a) *What constitutes change of ownership*—(1) *Incorporation*. The incorporation of an unincorporated FQHC constitutes change of ownership.

(2) *Merger*. The merger of the center corporation into another corporation, or the consolidation of two or more corporations, one of which is the center corporation, resulting in the creation of a new corporation, constitutes a change of ownership. (The merger of another corporation into the center corporation does not constitute change of ownership.)

(3) *Leasing*. The lease of all or part of an entity constitutes a change of ownership of the leased portion.

(b) *Notice to CMS*. A center which is contemplating or negotiating change of ownership must notify CMS.

(c) *Assignment of agreement*. When there is a change of ownership as specified in paragraph (a) of this section, the agreement with the existing center is automatically assigned to the new owner if it continues to meet the conditions to be a Federally qualified health center.

(d) *Conditions that apply to assigned agreements*. An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Compliance with applicable health and safety standards.

(2) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C of this subchapter.

§ 405.2446 Scope of services.

(a) For purposes of this section, the terms *rural health clinic* and *clinic* when they appear in the cross references in paragraph (b) of this section also mean Federally qualified health centers.

(b) FQHC services that are paid for under this subpart are outpatient services that include the following:

(1) Physician services specified in § 405.2412.

(2) Services and supplies furnished as an incident to a physician's professional services, as specified in § 405.2413.

(3) Nurse practitioner or physician assistant services specified in § 405.2414.

(4) Services and supplies furnished as an incident to a nurse practitioner or physician assistant services, as specified in § 405.2415.

(5) Clinical psychologist and clinical social worker services specified in § 405.2450.

(6) Services and supplies furnished as an incident to a clinical psychologist or clinical social worker services, as specified in § 405.2452.

(7) Visiting nurse services specified in § 405.2416.

(8) Nurse-midwife services specified in § 405.2401.

(9) Preventive primary services specified in § 405.2448 of this subpart.

(c) Federally qualified health center services are covered when provided in outpatient settings only, including a patient's place of residence, which may be a skilled nursing facility or a nursing facility or other institution used as a patient's home.

(d) Federally qualified health center services are not covered in a hospital, as defined in section 1861(e)(1) of the Act.

[57 FR 24979, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2448 Preventive primary services.

(a) Preventive primary services are those health services that—

(1) A center is required to provide as preventive primary health services under section 329, 330, and 340 of the Public Health Service Act;

(2) Are furnished by or under the direct supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner, clinical psychologist, clinical social worker, or a physician;

(3) In the case of a service, are furnished by a member of the center's health care staff who is an employee of the center or by a physician under arrangements with the center; and

(4) Except as specifically provided in section 1861(s) of the Act, include only drugs and biologicals that cannot be self-administered.

(b) Preventive primary services which may be paid for when provided by Federally qualified health centers are the following:

(1) Medical social services.

(2) Nutritional assessment and referral.

(3) Preventive health education.

(4) Children's eye and ear examinations.

(5) Prenatal and post-partum care.

(6) Perinatal services.

(7) Well child care, including periodic screening.

(8) Immunizations, including tetanus-diptheria booster and influenza vaccine.

(9) Voluntary family planning services.

(10) Taking patient history.

(11) Blood pressure measurement.

(12) Weight.

(13) Physical examination targeted to risk.

(14) Visual acuity screening.

(15) Hearing screening.

(16) Cholesterol screening.

(17) Stool testing for occult blood.

(18) Dipstick urinalysis.

(19) Risk assessment and initial counseling regarding risks.

(20) Tuberculosis testing for high risk patients.

(21) For women only.

(i) Clinical breast exam.

(ii) Referral for mammography; and

(iii) Thyroid function test.

(c) Preventive primary services do not include group or mass information programs, health education classes, or group education activities, including media productions and publications.

(d) Screening mammography is not considered a Federally qualified health center service, but may be provided at a Federally qualified health center if the center meets the requirements applicable to that service specified in § 410.34 of this subchapter. Payment is made under applicable Medicare requirements.

(e) Preventive primary services do not include eyeglasses, hearing aids, or preventive dental services.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2450 Clinical psychologist and clinical social worker services.

(a) For clinical psychologist or clinical social worker professional services to be payable under this subpart, the services must be—

(1) Furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC;

(2) Of a type that the clinical psychologist or clinical social worker who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a clinical social worker or clinical psychologist who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

(4) Covered if furnished by a physician.

(b) If State law prescribes a physician supervision requirement, it is met if the conditions specified in § 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of clinical psychologists or clinical social workers are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

(a) Services and supplies incident to a clinical psychologist's or clinical social worker's services are reimbursable under this subpart if the service or supply is—

(1) Of a type commonly furnished in a physician's office;

(2) Of a type commonly furnished either without charge or included in the Federally qualified health center's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist or clinical social worker;

(4) Furnished under the direct, personal supervision of a clinical psychologist, clinical social worker or physician; and

(5) In the case of a service, furnished by a member of the center's health care staff who is an employee of the center.

(b) The direct personal supervision requirement in paragraph (a)(4) of this section is met only if the clinical psychologist or clinical social worker is permitted to supervise such services under the written policies governing the Federally qualified health center.

PAYMENT FOR RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24976, 24977, June 12, 1992, unless otherwise noted.

§ 405.2460 Applicability of general payment exclusions.

The payment conditions, limitations, and exclusions set out in subpart C of this part, part 410 and part 411 of this chapter are applicable to payment for services provided by rural health clinics and Federally qualified health centers, except that preventive primary services, as defined in § 405.2448, are covered in Federally qualified health centers and not excluded by the provisions of section 1862(a) of the Act.

§ 405.2462 Payment for rural health clinic services and Federally qualified health clinic services.

(a) *General rules.* (1) RHCs and FQHCs are paid on the basis of 80 percent of an all-inclusive rate per visit determined by the fiscal intermediary for each beneficiary visit for covered services, subject to an annual payment limit.

(2) The fiscal intermediary determines the all-inclusive rate in accordance with this subpart and instructions issued by CMS.

(3) If an RHC is an integral and subordinate part of a hospital, it can receive an exception to the per-visit payment limit if the hospital has fewer than 50 beds as determined by using one of the following methods:

(i) The determination of the number of beds at § 412.105(b) of this chapter.

(ii) The hospital's average daily patient census count of those beds described in § 412.105(b) of this chapter, and the hospital meets all of the following conditions:

(A) It is a sole community hospital as determined in accordance with § 412.92 or 412.109(a) of this chapter.

(B) It is located in a level 8 or level 9 nonmetropolitan county using urban influence codes as defined by the U.S. Department of Agriculture.

(C) It has an average daily patient census that does not exceed 40.

(b) *Payment procedures.* To receive payment, an RHC or FQHC must follow the payment procedures specified in § 410.165 of this chapter.

(c) *Mental health limitation.* Payment for the outpatient treatment of mental, psychoneurotic, or personality disorders is subject to the limitations on payment in § 410.155(c) of this chapter.

[69 FR 74816, Dec. 24, 2003]

§ 405.2463 What constitutes a visit.

(a) *Visit.* (1) A visit is a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(2) For FQHCs, a visit also means a face-to-face encounter between a patient and a qualified clinical psychologist or clinical social worker.

(3) Encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when one of the following conditions exist:

(i) After the first encounter, the patient suffers illness or injury requiring additional diagnosis or treatment.

(ii) For FQHCs, the patient has a medical visit and an other health visit, as defined in paragraphs (b) and (c) of this section.

(4) *Payment.* (i) Medicare pays for two visits per day when the conditions in paragraph (a)(3) of this section are met.

(ii) In all other cases, payment is limited to one visit per day.

(b) *Medical visit.* For purposes of paragraph (a)(3) of this section, a medical visit is a face-to-face encounter between an FQHC patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(c) *Other health visit.* For purposes of paragraph (a)(3) of this section, an

other health visit is a face-to-face encounter between an FQHC patient and a clinical psychologist, clinical social worker, or other health professional for mental health services.

[61 FR 14657, Apr. 3, 1996]

§ 405.2464 All-inclusive rate.

(a) *Determination of rate.* (1) An all-inclusive rate is determined by the intermediary at the beginning of the reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by estimated total visits for rural health clinic or Federally qualified health center services.

(3) The rate determination is subject to any tests of reasonableness that may be established in accordance with this subpart.

(b) *Adjustment of rate.* (1) The intermediary, during each reporting period, periodically reviews the rate to assure that payments approximate actual allowable costs and visits for rural health clinic or Federally qualified health center services and adjusts the rate if:

(i) There is a significant change in the utilization of clinic or center services;

(ii) Actual allowable costs vary materially from the clinic or center's allowable costs; or

(iii) Other circumstances arise which warrant an adjustment.

(2) The clinic or center may request the intermediary to review the rate to determine whether adjustment is required.

§ 405.2466 Annual reconciliation.

(a) *General.* Payments made to a rural health clinic or a Federally qualified health center during a reporting period are subject to reconciliation to assure that those payments do not exceed or fall short of the allowable costs attributable to covered services furnished to Medicare beneficiaries during that period.

(b) *Calculation of reconciliation.* (1) The total reimbursement amount due the clinic or center for covered services furnished to Medicare beneficiaries is based on the report specified in § 405.2470(c)(2) and is calculated by the intermediary as follows:

(i) The average cost per visit is calculated by dividing the total allowable cost incurred for the reporting period by total visits for rural health clinic or Federally qualified health center services furnished during the period. The average cost per visit is subject to tests of reasonableness which may be established in accordance with this subpart.

(ii) The total cost of rural health clinic or Federally qualified health center services furnished to Medicare beneficiaries is calculated by multiplying the average cost per visit by the number of visits for covered rural health clinic or Federally qualified health center services by beneficiaries.

(iii) For rural health clinics, the total reimbursement due the clinic is 80 percent of the amount calculated by subtracting the amount of deductible incurred by beneficiaries that is attributable to rural health clinic services from the cost of these services. The reimbursement computation for Federally qualified health centers does not include a reduction related to the deductible because Federally qualified health center services are not subject to a deductible.

(iv) For rural health clinics and FQHCs, payment for pneumococcal and influenza vaccine and their administration is 100 percent of Medicare reasonable cost.

(2) The total reimbursement amount due is compared with total payments made to the clinic or center for the reporting period, and the difference constitutes the amount of the reconciliation.

(c) *Notice of program reimbursement.* The intermediary sends written notice to the clinic or center:

(1) Setting forth its determination of the total reimbursement amount due the clinic or center for the reporting period and the amount, if any, of the reconciliation; and

(2) Informing the clinic or center of its right to have the determination reviewed at a hearing under the procedures set forth in subpart R of this part.

(d) *Payment of reconciliation amount*—(1) *Underpayments.* If the total reimbursement due the clinic or center exceeds the payments made for the reporting period, the intermediary makes a lump-sum payment to the clinic or center to bring total payments into agreement with total reimbursement due the clinic or center.

(2) *Overpayments.* If the total payments made to a clinic or center for the reporting period exceed the total reimbursement due the clinic or center for the period, the intermediary arranges with the clinic or center for repayment through a lump-sum refund, or, if that poses a hardship for the clinic or center, through offset against subsequent payments or a combination of offset and refund. The repayment must be completed as quickly as possible, generally within 12 months from the date of the notice of program reimbursement. A longer repayment period may be agreed to by the intermediary if the intermediary is satisfied that unusual circumstances exist which warrant a longer period.

[57 FR 24976, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2468 Allowable costs.

(a) *Applicability of general Medicare principles.* In determining whether and to what extent a specific type or item of cost is allowable, such as interest, depreciation, bad debts and owner compensation, the intermediary applies the principles for reimbursement of provider costs, as set forth in part 413 of this subchapter.

(b) *Typical rural health clinic and Federally qualified health center costs.* The following types and items of cost are included in allowable costs to the extent that they are covered and reasonable:

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, nurse-midwife, visiting nurse, qualified clinical psychologist, and clinical social worker who owns, is employed by, or furnishes services under contract to an FQHC. (RHCs are not paid for services furnished by contracted individuals other than physicians.)

(2) Compensation for the duties that a supervising physician is required to perform under the agreement specified in § 491.8 of this chapter.

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, or clinical social worker.

(4) Overhead costs, including clinic or center administration, costs applicable to use and maintenance of the entity, and depreciation costs.

(5) Costs of services purchased by the clinic or center.

(c) *Tests of reasonableness for rural health clinic cost and utilization.* Tests of reasonableness authorized by sections 1833(a) and 1861(v)(1)(A) of the Act may be established by CMS or the carrier with respect to direct or indirect overall costs, costs of specific items and services, or costs of groups of items and services. Those tests include, but are not limited to, screening guidelines and payment limitations.

(d) *Screening guidelines.* (1) Costs in excess of amounts established by the guidelines are not included unless the clinic or center provides reasonable justification satisfactory to the intermediary.

(2) Screening guidelines are used to assess the costs of services, including the following:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, and nurse-midwives.

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, and clinical social workers.

(iii) The level of administrative and general expenses.

(iv) Staffing (for example, the ratio of other clinic or center personnel to physicians, physician assistants, and nurse practitioners).

(v) The reasonableness of payments for services purchased by the clinic or center, subject to the limitation that the costs of physician services purchased by the clinic or center may not exceed amounts determined under the applicable provisions of subpart E of part 405 or part 415 of this chapter.

(e) *Payment limitations.* Limits on payments may be set by CMS, on the

basis of costs estimated to be reasonable for the provision of such services.

(f) *Graduate medical education.* (1) Effective for that portion of cost reporting periods occurring on or after January 1, 1999, if an RHC or an FQHC incurs ''all or substantially all'' of the costs for the training program in the nonhospital setting as defined in § 413.75(b) of this chapter, the RHC or FQHC may receive direct graduate medical education payment for those residents.

(2) Direct graduate medical education costs are not included as allowable cost under § 405.2466(b)(1)(i); and therefore, are not subject to the limit on the all-inclusive rate for allowable costs.

(3) Allowable graduate medical education costs must be reported on the RHC's or the FQHC's cost report under a separate cost center.

(4) Allowable graduate medical education costs are non-reimbursable if payment for these costs are received from a hospital or a Medicare+Choice organization.

(5) Allowable direct graduate medical education costs under paragraphs (f)(6) and (f)(7)(i) of this section, are subject to reasonable cost principles under part 413 and the reasonable compensation equivalency limits in §§ 415.60 and 415.70 of this chapter.

(6) The allowable direct graduate medical education costs are those costs incurred by the nonhospital site for the educational activities associated with patient care services of an approved program, subject to the redistribution and community support principles in § 413.85(c).

(i) The following costs are allowable direct graduate medical education costs to the extent that they are reasonable—

(A) The costs of the residents' salaries and fringe benefits (including travel and lodging expenses where applicable).

(B) The portion of teaching physicians' salaries and fringe benefits that are related to the time spent teaching and supervising residents.

(C) Facility overhead costs that are allocated to direct graduate medical education.

(ii) The following costs are not allowable graduate medical education costs—

(A) Costs associated with training, but not related to patient care services.

(B) Normal operating and capital-related costs.

(C) The marginal increase in patient care costs that the RHC or FQHC experiences as a result of having an approved program.

(D) The costs associated with activities described in § 413.85(h) of this chapter.

(7) Payment is equal to the product of—

(i) The RHC's or the FQHC's allowable direct graduate medical education costs; and

(ii) Medicare's share, which is equal to the ratio of Medicare visits to the total number of visits (as defined in § 405.2463).

(8) Direct graduate medical education payments to RHCs and FQHCs made under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24977, June 12, 1992; 60 FR 63176, Dec. 8, 1995; 61 FR 14658, Apr. 3, 1996; 63 FR 41002, July 31, 1998; 66 FR 39932, Aug. 1, 2001; 70 FR 47484, Aug. 12, 2005]

§ 405.2470 Reports and maintenance of records.

(a) *Maintenance and availability of records.* The rural health clinic or Federally qualified health center must:

(1) Maintain adequate financial and statistical records, in the form and containing the data required by CMS, to allow the intermediary to determine payment for covered services furnished to Medicare beneficiaries in accordance with this subpart;

(2) Make the records available for verification and audit by HHS or the General Accounting Office;

(3) Maintain financial data on an accrual basis, unless it is part of a governmental institution that uses a cash basis of accounting. In the latter case, appropriate depreciation on capital assets is allowable rather than the expenditure for the capital asset.

(b) *Adequacy of records.* (1) The intermediary may suspend reimbursement if

it determines that the clinic or center does not maintain records that provide an adequate basis to determine payments under Medicare.

(2) The suspension continues until the clinic or center demonstrates to the intermediary's satisfaction that it does, and will continue to, maintain adequate records.

(c) *Reporting requirements*—(1) *Initial report*. At the beginning of its initial reporting period, the clinic or center must submit an estimate of budgeted costs and visits for rural health clinic or Federally qualified health center services for the reporting period, in the form and detail required by CMS, and such other information as CMS may require to establish the payment rate.

(2) *Annual reports*. Within 90 days after the end of its reporting period, the clinic or center must submit, in such form and detail as may be required by CMS, a report of:

(i) Its operations, including the allowable costs actually incurred for the period and the actual number of visits for rural health clinic or Federally qualified health center services furnished during the period; and

(ii) The estimated costs and visits for rural health clinic services or Federally qualified health center services for the succeeding reporting period and such other information as CMS may require to establish the payment rate.

(3) *Late reports*. If the clinic or center does not submit an adequate annual report on time, the intermediary may reduce or suspend payments to preclude excess payment to the clinic or center.

(4) *Inadequate reports*. If the clinic or center does not furnish a report or furnishes a report that is inadequate for the intermediary to make a determination of program payment, CMS may deem all payments for the reporting period to be overpayments.

(5) *Postponement of due date*. For good cause shown by the clinic or center, the intermediary may, with CMS's approval, grant a 30-day postponement of the due date for the annual report.

(6) *Reports following termination of agreement or change of ownership*. The report from a clinic or center which voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change in ownership (see §§ 405.2436–405.2438) is due no later than 45 days following the effective date of the termination of agreement or change of ownership.

§ 405.2472 Beneficiary appeals.

A beneficiary may request a hearing by an intermediary (subject to the limitations and conditions set forth in subpart H of this part) if:

(a) The beneficiary is dissatisfied with an intermediary's determination denying a request for payment made on his or her behalf by a rural health clinic or Federally qualified health center; or

(b) The beneficiary is dissatisfied with the amount of payment; or

(c) The beneficiary believes the request for payment is not being acted upon with reasonable promptness.

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24978, June 12, 1992]

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 48 FR 12536, Mar. 25, 1983, unless otherwise noted. Redesignated at 51 FR 41338, Nov. 14, 1986.

Subpart A—General Provisions

§406.1 Statutory basis.

Sections 226, 226A, 1818 and 1818A of the Social Security Act and section 103 of Public Law 89–97 establish the conditions for entitlement to hospital insurance benefits. Sections 202 (t) and (u) of the Act specify limitations that apply to certain aliens and to persons convicted of certain offenses.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 56 FR 38078, Aug. 12, 1991]

§406.2 Scope.

Subparts A through D of this part specify the conditions of eligibility for hospital insurance and set forth certain specific conditions that affect entitlement to benefits. Hospital insurance is authorized under Part A of title XVIII and is also referred to as Medicare Part A. It includes inpatient hospital care, posthospital SNF care, home health services, and hospice care.

[48 FR 56026, Dec. 16, 1983, as amended at 50 FR 33033, Aug. 16, 1985. Redesignated and amended at 51 FR 41338, Nov. 14, 1986]

§406.3 Definitions.

First month of eligibility means the first month in which an individual meets all the requirements for entitlement to hospital insurance except application or enrollment if that is required.

First month of entitlement means the first month for which the individual meets all the requirements for entitlement to Part A benefits.

Insured individual means an individual who has the number of quarters of coverage required for monthly social security benefits.

Quarter of coverage means a calendar quarter that is counted toward the number of covered quarters required to make the individual eligible for monthly social security benefits. A quarter is counted if during that quarter (or that calendar year) the individual earned a required minimum amount of money. (For details, see 20 CFR part 404, subpart B.)

§406.5 Basis of eligibility and entitlement.

(a) *Hospital insurance without premiums*. Hospital insurance is available to most individuals without payment of a premium if they:

(1) Are age 65 or over, or

(2) Have received social security or railroad retirement disability benefits for 25 months; or

(3) Have end-stage renal disease. Subpart B of this part explains the requirements such individuals must meet to obtain hospital insurance without premiums.

(b) *Premium hospital insurance*. Many individuals who are age 65 or over, but do not meet the requirements set forth in subpart B of this part, and certain individuals under age 65, may obtain the benefits by paying a premium. Section 406.20 of this part explains the requirements individuals must meet to obtain premium hospital insurance.

[48 FR 12536, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 56 FR 38078, Aug. 12, 1991]

§406.6 Application or enrollment for hospital insurance.

(a) *Basic provision*. In most cases, eligibility for Medicare Part A is a result of entitlement to monthly social security or railroad retirement cash benefits or eligibility for monthly social security cash benefits. This section specifies the individuals who need not file an application to become entitled to

hospital insurance, those who must file an application, and those who must enroll.

(b) *Individuals who need not file an application for hospital insurance.* An individual who meets any of the following conditions need not file an application for hospital insurance:

(1) Is under age 65 and has been entitled, for more than 24 months, to monthly social security or railroad retirement benefits based on disability.

(2) At the time of attainment of age 65, is entitled to monthly social security or railroad retirement benefits.

(3) Establishes entitlement to monthly social security or railroad retirement benefits at any time after attaining age 65.

(c) *Individuals who must file an application for hospital insurance.* An individual must file an application for hospital insurance if he or she seeks entitlement to hospital insurance on the basis of—

(1) The transitional provisions set forth in § 406.11;

(2) Deemed entitlement to disabled widow's or widower's benefit under certain circumstances as provided in § 406.12;

(3) A diagnosis of end-stage renal disease, as specified in § 406.13;

(4) Effective January 1, 1981, eligibility for social security cash benefits, as specified in § 406.10(a)(3), if the individual has attained age 65 without applying for those benefits; or

(5) The special provisions applicable to government employment as set forth in § 406.15.

(d) *When application is deemed to be filed.* (1) An application based on the transitional provisions or on ESRD is deemed to be filed in the first month of eligibility if it is filed not more than 3 months before the first month, and is retroactive to that month if filed within 12 months after the first month. An application filed more than 12 months after the first month of eligibility is retroactive to the 12th month before the month it is filed.

(2) An application for deemed entitlement to disabled widow's or widower's benefits, that is filed before the first month in which the individual meets all conditions of entitlement for this benefit, will be deemed a valid application if those conditions are met before an initial determination, reconsideration, or hearing decision is made on the application. If the conditions are met after the date of any hearing decision, a new application will have to be filed. An application validly filed within 12 months after the first month of eligibility is retroactive to that first month. If filed more than 12 months after that first month, it is retroactive to the 12th month before the month of filing.

(3) Effective June 8, 1980, an application based on eligibility for social security benefits at or after age 65, that is filed before the first month in which the individual meets all eligibility conditions for this benefit, will be deemed a valid application if those conditions are met before an initial determination, reconsideration, or hearing decision is made on the application. If the conditions are met after the date of any hearing decision, a new application will have to be filed.

(4) Effective March 1, 1981, an application under § 406.10 that is validly filed within 6 months after the first month of eligibility is retroactive to that first month. If filed more than 6 months after that first month, it is retroactive to the 6th month before the month of filing.

(e) *Individuals who must enroll for hospital insurance.* An individual who must pay a monthly premium for hospital insurance must enroll in accordance with the procedures set forth in § 406.21.

[48 FR 12536, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 53 FR 47202, Nov. 22, 1988; 61 FR 40345, Aug. 2, 1996]

§ 406.7 Forms to apply for entitlement under Medicare Part A.

The following forms, available free of charge by mail from CMS or at any Social Security branch or district office, are used to apply for Medicare entitlement under the circumstances indicated:

CMS–18–F–5—Application for Hospital Insurance Entitlement. (For use by individuals who are not eligible for retirement benefits under Title II of the Social Security Act or under the Railroad Retirement Act. This form may also be used for enrollment in the supplementary medical insurance program.)

CMS–43—Application for Health Insurance Benefits under Medicare for Individuals with End Stage Renal Disease (ESRD). (An initial application for entitlement by individuals with ESRD).

As an alternative, an individual may use the application for monthly social benefits to apply also for Medicare entitlement if he or she is eligible for hospital insurance at that time.

[53 FR 6633, Mar. 2, 1988]

Subpart B—Hospital Insurance Without Monthly Premiums

§ 406.10 Individual age 65 or over who is entitled to social security or railroad retirement benefits, or who is eligible for social security benefits.

(a) *Requirements.* An individual is entitled to hospital insurance benefits under section 226 of the Act if he or she has attained aged 65 and is:

(1) Entitled to monthly social security benefits under section 202 of the Social Security Act;

(2) A qualified railroad retirement beneficiary who has been certified as such to the Social Security Administration by the Railroad Retirement Board in accordance with section 7(d) of the Railroad Retirement Act of 1974; or

(3) Effective January 1, 1981, eligible for monthly social security benefits under section 202 of the Act and has filed an application for hospital insurance.

(b) *Beginning and end of entitlement.* (1) Entitlement begins with the first day of the first month in which the individual meets the requirements of paragraph (a) of this section.

(2) Entitlement continues until the individual dies or no longer meets the requirements of paragraph (a) of this section. An individual is not entitled to railroad retirement benefits and is neither entitled to, nor eligible for, monthly social security benefits in the month in which he or she dies. However, an individual who meets all other requirements for hospital insurance entitlement is entitled to hospital insurance in the month in which he or she dies if he or she—

(i) Would have been entitled to monthly railroad retirement benefits or social security benefits in that month if he or she had not died; or

(ii) Has filed an application for hospital insurance and would have been eligible for monthly social security benefits in that month if he or she had not died.

§ 406.11 Individual age 65 or over who is not eligible as a social security or railroad retirement benefits beneficiary, or on the basis of government employment.

(a) *Basis.* Section 103 of the law that established the Medicare program in 1965 (Pub. L. 89–97) provided for eligibility for certain individuals who were age 65 or would soon attain age 65 but would not be able to qualify for social security or railroad retirement benefits.

(b) *Requirements.* Unless he or she is excluded under paragraph (c) of this section, an individual age 65 or over who does not meet the requirements of § 406.10 or § 406.15 (and who would not meet those requirements if he or she filed an application), is entitled to Medicare Part A benefits if he or she meets the following requirements:

(1) *Age and quarters of coverage.* (i) He or she attained age 65 before 1968; or

(ii) If he or she attained age 65 in 1968 or later, he or she must have at least 3 quarters of coverage for each year that elapsed after 1966 and before the year in which he or she attained age 65. (The quarters of coverage may have been acquired at any time, not necessarily during the elapsed years.)

(2) *Residence and citizenship.* He or she is a resident of the United States and—

(i) A citizen of the United States; or

(ii) An alien lawfully admitted for permanent residence who has continuously resided in the United States for 5 years immediately preceding the first month in which he or she meets all other requirements for entitlement to hospital insurance.

(3) *Application.* He or she has filed an application for Medicare Part A no earlier than the third month before the first month of eligibility.

(c) *Bases for exclusion.* An individual who meets the requirements of paragraph (b) of this section is excluded from Medicare Part A if he or she—

(1) Has been convicted of spying, sabotage, or treason, sedition, and subversive action under chapter 37, 105, or 115 of title 18 of the United States Code;

(2) Has been convicted of conspiracy to establish a dictatorship under section 4 of the Internal Security Act of 1950;

(3) On February 16, 1965, was or could have been covered under the Federal Employees Health Benefits Act (FEHBA) of 1959; or

(4) In his or her first month of eligibility;

(i) Is covered by an enrollment under the FEHBA; or

(ii) Could have been covered by an enrollment under that Act if he or she (or any other person who could provide him or her with coverage) was a Federal employee at any time after February 15, 1965, and had enrolled and retained coverage under that Act.

(d) *End of exclusion*. An individual excluded under paragraph (c)(3) or (4) of this section can become entitled beginning with the first month in which he or she loses the right to FEHBA coverage solely because he or she or the other person leaves Federal employment.

(e) *Beginning and end of entitlement*. (1) Entitlement begins—

(i) In the first month of eligibility if the application is filed no later than 12 months after the first month of eligibility:

(ii) In the 12th month before the month of application if the application is filed more than 12 months after the first month of eligibility.

(2) Entitlement continues until death or until the month before the month in which the individual becomes entitled under § 406.10 or § 406.15.

[48 FR 12536, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 53 FR 47202, Nov. 22, 1988]

§ 406.12 Individual under age 65 who is entitled to social security or railroad retirement disability benefits.

(a) *Basic requirements*. An individual under age 65 is entitled to hospital insurance benefits if, for 25 months, he or she has been—

(1) Entitled or deemed entitled to social security disability benefits as an insured individual, child, widow, or widower who is ''under a disability'' or

(2) A disabled qualified beneficiary certified under Section 7(d) of the Railroad Retirement Act.

(b) *Previous periods of disability benefits entitlement*. Months of a previous period of entitlement or deemed entitlement to disability benefits count toward the 25-month requirement if any of the following conditions is met:

(1) Entitlement was as an insured individual or a disabled qualified railroad retirement beneficiary, and the previous period ended within the 60 months preceding the month in which the current disability began.

(2) Entitlement was as a disabled child, widow, or widower, and the previous period ended within the 84 months preceding the month in which the current disability began.

(3) The previous period ended on or after March 1, 1988 and the current impairment is the same as, or directly related to, the impairment on which the previous period of entitlement was based.

(c) *Deemed entitlement to disabled widow's or widower's monthly benefits*.

(1) *Purpose*. The provisions of paragraphs (c) (2), (3), and (4) of this section are intended to enable individuals—

(i) To meet the 25-month requirement of paragraph (a) of this section; or

(ii) To retain hospital insurance entitlement when they are no longer entitled to monthly disability benefits.

(2) *Deemed entitlement for certain individuals entitled to old-age insurance benefits*. An individual who becomes entitled to monthly old-age insurance benefits before age 65, is, by law, precluded from establishing or retaining entitlement to disabled widow's or widower's monthly benefits. However, for purposes of meeting the 25-month requirement, a widow or widower who meets all other requirements for disability benefits and is excluded solely because of entitlement to old-age insurance benefits, shall be deemed to be (or to continue to be) entitled to disability benefits. A widow or widower who is not entitled to disability benefits for the month before attaining age 60 must file two applications, one for old-age insurance benefits and one for hospital insurance.

(3) *Deemed entitlement for certain individuals entitled to mother's benefits.* An individual entitled to mother's insurance benefits under section 202(g) of the Social Security Act cannot at the same time be entitled to disabled widow's benefits. However, if she applies for hospital insurance, she will be deemed to be entitled to disabled widow's monthly benefits in the first month (of the 12 months before application) in which she would have been entitled to those benefits if she had filed an application for them.

(4) *Deemed entitlement for certain individuals entitled to father's benefits.* An individual who is entitled to father's insurance benefits under section 202(g) of the Act cannot at the same time be entitled to disabled widower's benefits. However, if he applies for hospital insurance benefits, he will be deemed to be entitled to disabled widower's monthly benefits as follows:

(i) If he applied for hospital insurance benefits before May 1984, he was deemed entitled to disabled widower's benefits for any month after April 1981 for which he would have been entitled to those benefits if he had filed an application for them.

(ii) If he applies for hospital insurance benefits in or after May 1984, he is deemed entitled to disabled widower's benefits for any month, up to 12 months before the month of application, for which he would have been entitled to those benefits if he had filed an application for them.

(iii) Hospital insurance entitlement under this paragraph (c)(4) could not begin before May 1983.

(5) *Deemed retroactive entitlement for certain disabled widows and widowers.* In some cases, disabled widows or widowers cannot become entitled to monthly cash benefits before the month in which they file application. However, for purposes of meeting the 25-month requirement, disability benefit entitlement will be deemed to have begun with the earliest month (of the 12 months before the application for cash benefits) in which the individual met all the requirements except the filing of an application. (This provision is effective for applications filed on or after January 1, 1978.)

(d) *When entitlement begins and ends.* (1) Entitlement to hospital insurance begins with the 25th month of an individual's entitlement or deemed entitlement to disability benefits. Although an individual is not entitled to disability benefits for the month in which he or she dies, for purposes of this paragraph the individual will be deemed to be entitled for the month of death.

(2) Except as provided in paragraph (e) of this section, entitlement to hospital insurance ends with the earliest of the following:

(i) The last day of the last month in which he or she was entitled or deemed entitled to disability benefits or was qualified as a disabled railroad retirement beneficiary, if he or she was notified of the termination of entitlement before that month.

(ii) The last day of the month following the month in which he or she is mailed a notice that his or her entitlement or deemed entitlement to disability benefits, or his or her status as a qualified disabled railroad retirement beneficiary, has ended.

(iii) The last day of the month before the month he or she attains age 65. (An individual who is entitled to social security or railroad retirement cash benefits for the month of attainment of age 65 is automatically entitled to hospital insurance under § 406.10.)

(iv) The day of death.

(e) *Continuation of Medicare entitlement when disability benefit entitlement* ends because of substantial gainful activity (SGA)—(1) *Definitions.* As used in this section—

Trial work period means the 9-month period provided under title II of the Act and as defined 20 CFR 404.1592, during which the individual may test his or her ability to work and still receive disability cash benefits; and

Reentitlement period means a period as defined in 20 CFR 404.1592a that begins with the first month after the trial work period and ends with the 36th month after the trial work period or, if earlier, with the first month in which the impairment no longer exists or is no longer disabling. (During the reentitlement period, benefits may be discontinued because of SGA. However, if SGA is later discontinued, benefits

may be reinstated without a new application and a new disability determination.)

(2) *Duration of continued Medicare entitlement.* If an individual's entitlement to disability benefits or status as a qualified disabled railroad retirement beneficiary ends because he or she engaged in, or demonstrated the ability to engage in, substantial gainful activity after the 36 months following the end of the trial work period, Medicare entitlement continues until the earlier of the following:

(i) The last day of the 78th month following the first month of substantial gainful activity occurring after the 15th month of the individual's reentitlement period or, if later, the end of the month following the month the individual's disability benefit entitlement ends.

(ii) The last day of the month following the month in which notice is mailed to the individual indicating that he or she is no longer entitled to hospital insurance because of an event or circumstance (for example, there has been medical improvement, or the disabled widow has remarried) that would terminate disability benefit entitlement if it had not already been terminated because of substantial gainful activity.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 53 FR 47202, Nov. 22, 1988; 56 FR 38078, Aug. 12, 1991; 56 FR 50058, Oct. 3, 1991; 61 FR 40345, Aug. 2, 1996; 69 FR 57225, Sept. 24, 2004]

§ 406.13 Individual who has end-stage renal disease.

(a) *Statutory basis and applicability.* This section explains the conditions of entitlement to hospital insurance benefits on the basis of end-stage renal disease, and specifies the beginning and end of the period of entitlement. It implements section 226A of the Social Security Act.

(b) *Definitions.* As used in this section:

End-stage renal disease (ESRD) means that stage of kidney impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.

Child or *spouse* means a child or spouse whose relationship to the parent or spouse meets the relationship requirements for entitlement to child's monthly social security benefits or to wife's, husband's, widow's, widower's, mother's or father's monthly benefits, as set forth in 20 CFR part 404. However, the duration of relationship requirements apply only to divorced spouses. (See 20 CFR 404.331.)

Dependent child means a person who, on the first day he or she has end-stage renal disease, is unmarried and meets the dependency requirements for entitlement to child's social security benefits on the basis of a parent's earnings (see 20 CFR 404.350–404.365) and who—

(1) Is under age 22;

(2) Is under a disability that began before age 22; or

(3) Is under age 26, is receiving at least one-half support from that parent, and has continuously received at least one-half support from that parent since the day before attaining age 22.

One-half support means regular contributions, in cash or in kind, that equals or exceeds one-half of the child's total support.

(c) *Requirements.* An individual is entitled to hospital insurance benefits if—

(1) He or she is medically determined to have ESRD;

(2) He or she is:

(i) Fully or currently insured under the social security program (title II of the Act) or would be fully or currently insured if his or her employment (after 1936) as defined under the Railroad Retirement Act were considered ''employment'' under the Social Security Act;

(ii) Entitled to monthly social security or railroad retirement benefits; or

(iii) The spouse or dependent child of a person who meets the requirements of paragraph (c)(2)(i) or (c)(2)(ii) of this section;

(3) He or she has filed an application for Medicare Part A; and

(4) He or she has satisfied the waiting period explained in paragraph (e) of this section.

(d) *Filing an application.* (1) An individual may obtain an application form, and help in completing it, from any social security office.

(2) An application is not valid if it is filed earlier than the third month before the month in which the individual meets the conditions of paragraphs (c)(1), (c)(2), and (c)(4) of this section.

(3) If an individual who has ESRD dies before he or she has filed an application, or is unable to file because of physical or mental condition, a relative or other person responsible for his or her affairs may file in his or her behalf. If a responsible person is not available, the hospital or dialysis facility that furnished treatment may file the application.

(e) *Beginning of entitlement*—(1) *Basic limitations*. Entitlement can begin no earlier than the first month in which the individual meets the conditions specified in paragraph (c) of this section, or the 12th month before the month of application, whichever is later.

(2) *Waiting period*. Entitlement begins on the first day of the third month after the month in which the individual initiates a regular course of renal dialysis, if the course is maintained throughout the waiting period, unless entitlement would begin earlier under paragraph (e) (3) or (4) of this section. This means that if dialysis began in January, entitlement would begin April 1.

(3) *Exceptions: Early kidney transplant*. If the individual receives a transplant, entitlement begins with the first day of the month in which the transplant was performed. However, if the individual is admitted as an inpatient to a hospital that is an approved renal transplantation center or renal dialysis center (see § 405.2102) for procedures preliminary to transplant surgery, entitlement begins—

(i) On the first day of the month in which he or she initially enters the hospital, if the transplant is performed in that month or in either of the next 2 months; or

(ii) On the first day of the second month before the month of kidney transplantation, if the transplant is delayed more than 2 months after the month of initial hospital stay.

For example, if an individual enters the hospital in January, and the transplant is performed in January, February, or March, entitlement would begin January 1. However, if the transplant is performed in April, entitlement would begin February 1.

(4) *Exceptions: Self-dialysis training*. Entitlement begins on the first day of the month in which a regular course of renal dialysis began if:

(i) Before the end of the waiting period, the individual participates in a self-dialysis training program offered by a participating Medicare facility that is approved to provide such training;

(ii) The patient's physician has certified that it is reasonable to expect the individual will complete the training program and will self-dialyze on a regular basis; and

(iii) The regular course of dialysis is maintained throughout the time that would otherwise be the waiting period (unless it is terminated earlier because the individual dies).

(f) *End of entitlement*. Entitlement ends with—

(1) The end of the 12th month after the month in which a regular course of dialysis ends; or

(2) The end of the 36th month after the month in which the individual has received a kidney transplant.

(g) *Resumption of entitlement*. Entitlement is resumed under the following conditions:

(1) An individual who initiates a regular course of renal dialysis or has a kidney transplant during the 12-month period after the previous course of dialysis ended is entitled to Part A benefits and eligible to enroll in Part B with the month the regular course of dialysis is resumed or the month the kidney is transplanted.

(2) An individual who initiates a regular course of renal dialysis or has a kidney transplant during the 36-month period after an earlier kidney transplant is entitled to Part A benefits and eligible to enroll in Part B with the month the regular course of dialysis begins or with the month the subsequent kidney transplant occurs.

(3) An individual who initiates a regular course of renal dialysis more than 12 months after the previous course of regular dialysis ended or more than 36 months after the month of a kidney transplant is eligible to enroll in Part A and Part B with the month in which

the regular course of dialysis is resumed. If he or she is otherwise entitled under the conditions specified in paragraph (c) of this section, including the filing of an application, entitlement begins with the month in which dialysis is initiated or resumed, without a waiting period, subject to the limitations of paragraph (e)(1) of this section.

[48 FR 12536, Mar. 25, 1983, as amended at 60 FR 22535, May 8, 1995]

§ 406.15 Special provisions applicable to Medicare qualified government employment.

(a) *Definition.* As used in this section, *Medicare-qualified government employment* means Federal, State, or local government employment that is subject only to the hospital insurance portion of the tax imposed by the Federal Insurance Contributions Act (F.I.C.A.). This includes—

(1) Wages paid for Federal employment after December 1982.

(2) Wages paid to State and local government employees hired after March 31, 1986.

(3) Wages paid to State and local government employees hired before April 1, 1986 but whose employment after March 31, 1986 is covered, for Medicare purposes only, under an agreement under section 218 of the Act.

(b) *Crediting of wages that are taxable only for Medicare purposes.* Medicare qualified government employment is credited in the same way and in the same amount as social security covered employment is credited for monthly social security cash benefit purposes. However, since only the Medicare portion (not the social security portion) of the F.I.C.A. tax is imposed, Medicare qualified government employment does not help qualify the individual for monthly Social Security cash benefits.

(c) *Required quarters of coverage.* (1) To qualify for hospital insurance on the basis of Medicare qualified government employment, an individual must have the number of quarters of coverage necessary to qualify for hospital insurance under § 406.10, § 406.12, or § 406.13.

(2) An individual who has worked in Medicare qualified government employment may qualify for hospital insurance on the basis of Medicare qualified government employment exclusively, or a combination of Medicare qualified government employment and social security covered employment.

(d) *Transitional provision for Federal employment.* Any individual who was a Federal employee at any time both during and before January 1983 will receive credit for quarters of Federal employment before January 1983 without paying tax. This transitional provision applies even if the Federal employee did not receive Federal wages for January 1983, for instance, because he or she was on approved leave without pay or on loan to a State or foreign agency.

(e) *Conditions of entitlement.* An individual who has worked in Medicare qualified government employment (or any related individual who would be entitled to social security cash benefits on the employee's record if Medicare qualified government employment qualified for those benefits) is entitled to hospital insurance benefits if he or she—

(1) Would meet the requirements of § 406.10, § 406.12, or § 406.13 if Medicare qualified government employment were social security covered employment; and

(2) Has filed an application for hospital insurance.

For purposes of this section not more than 12 months before the month of application may be counted towards the 25-month qualifying period specified in § 406.12(a).

(f) *Beginning and end of entitlement*—(1) *Basic rule.* Subject to the limitations specified in paragraph (f)(2) and (f)(3) of this section, entitlement begins and ends as specified in § 406.10, § 406.12 or § 406.13, whichever is used to establish hospital insurance entitlement for the Federal, State, or local government employee or related individual.

(2) *Limitations: Federal government employment.* (i) Hospital insurance entitlement based on Federal employment could not begin before January 1983.

(ii) No months before January 1983 may be used to satisfy the qualifying period required for entitlement based on disability.

(3) *Limitations: State and local government employment.* (i) Hospital insurance

entitlement based on State or local government employment cannot begin before April 1986.

(ii) No months before April 1986 may be used to satisfy the qualifying period required for entitlement based on disability.

[53 FR 47202, Nov. 22, 1988]

Subpart C—Premium Hospital Insurance

§ 406.20 Basic requirements.

(a) *General provisions.* Hospital insurance benefits are available to most individuals age 65 or over and to certain individuals under age 65 who do not qualify for those benefits under subpart B of this part and are willing to pay a monthly premium. This is called premium hospital insurance.

(b) *Eligibility of individuals age 65 or over to enroll for premium hospital insurance.* Any individual is eligible to enroll for Medicare Part A if he or she—

(1) Has attained age 65;

(2) Is a resident of the United States and is either—

(i) A citizen of the United States; or

(ii) An alien lawfully admitted for permanent residence who has resided in the United States continuously for the 5-year period immediately preceding the month in which he or she meets all other requirements;

(3) Is not eligible for Part A benefits under subpart B of this part; and

(4) Is entitled to supplementary medical insurance (Part B of Medicare) or is eligible and has enrolled for it during an enrollment period.

(c) *Eligibility of individuals under age 65 to enroll for premium hospital insurance.* An individual who has not attained age 65 is eligible to enroll for Medicare Part A if he or she meets the following conditions:

(1) Has been entitled to Medicare Part A (under § 406.12 or § 406.15) on the basis of entitlement or deemed entitlement to social security disability benefits, as provided under section 226(b) of the Act.

(2) Continues to have a disabling physical or mental impairment.

(3) Loses entitlement to disability benefits (and therefore also loses entitlement to Medicare Part A under § 406.12) solely because his or her earnings exceed the amount allowed under the social security regulations pertaining to ''substantial gainful activity'' (20 CFR 404.1571–404.1574); and

(4) Is not otherwise entitled to Medicare Part A.

[56 FR 38078, Aug. 12, 1991; 56 FR 50058, Oct. 3, 1991]

§ 406.21 Individual enrollment.

(a) *Basic provision.* An individual who meets the requirements of § 406.20 (b) or (c) may enroll for premium hospital insurance only during his or her ''initial enrollment period'', a ''general enrollment period'', a ''special enrollment period'', or, for HMO/CMP enrollees, a ''transfer enrollment period'', as set forth in paragraphs (b) through (f) of this section.

(b) *Initial enrollment periods*—(1) *Initial enrollment period for individual age 65 or over.* The initial enrollment period extends for 7 months, from the third month before the month the individual first meets the requirements of § 406.20 (b)(1) through (b)(3) through the third month after that first month of eligibility.

(2) *Initial enrollment period of individual under age 65.* The initial enrollment period begins with the month in which the individual receives notice that entitlement to Medicare Part A will end because he or she has lost entitlement to disability benefits solely because of earnings in excess of the amounts allowed under the social security regulations on substantial gainful activity (20 CFR 404.1571–404.1574). It continues for 7 full months after that month.

(c) *General enrollment period.* (1) Except as specified in paragraph (c)(4) of this section, the general enrollment period extends from January 1 to March 31 of each calendar year.

(2) General enrollment periods are for individuals who do not enroll during the special enrollment period, who failed to enroll during the initial enrollment period, or whose previous period of entitlement had terminated.

(3) If the individual enrolls or reenrolls during a general enrollment period, his or her entitlement begins on July 1 of the calendar year.

(4) During the period April 1 through September 30, 1981, the general enrollment period was any time after the end of the individual's initial enrollment period. Any eligible individual whose initial enrollment period has ended, or whose previous period of entitlement had terminated, could enroll or reenroll during that 6-month period.

(d) *''Deemed'' initial enrollment period for individual age 65 or over.* (1) If an individual who has attained age 65 fails to enroll during the initial enrollment period because of reliance on incorrect documentary information which led him or her to believe that he or she was not yet age 65, an initial enrollment period may be established for him or her as though he or she had attained age 65 on the date indicated by the incorrect documentary information.

(2) The deemed initial enrollment period will be used to determine the individual's premium and right to enroll in a general enrollment period if such use is advantageous to the individual.

(e) [Reserved]

(f) *Transfer enrollment period for HMO/CMP enrollees.* (1) *Terminology. HMO* or *CMP* means an eligible organization as defined in § 417.401 which has a contract with CMS under part 417, subpart L of this chapter.

(2) *Basic rule.* Effective February 1, 1991, individuals enrolled in an HMO or CMP under part 417, subpart K of this chapter who meet the requirements of § 406.20(b) may enroll in premium hospital insurance during a transfer enrollment period. This transfer enrollment period begins with any month or any part of a month in which the individual is enrolled in an HMO or CMP and ends with the last day of the 8th consecutive month in which the individual is no longer enrolled in the HMO or CMP.

(3) *Effective date of coverage.* (i) If the individual enrolls in premium hospital insurance while still enrolled in an HMO or CMP, or during the first month that he or she is no longer enrolled in the HMO or CMP, part A coverage will begin on the first day of the month of part A enrollment, or, at the option of the individual, on the first day of any of the following 3 months.

(ii) If the individual enrolls in premium hospital insurance during any of the last 7 months of the transfer enrollment period, coverage will begin on the first day of the month after the month of enrollment.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 53 FR 47203, Nov. 22, 1988; 56 FR 38079, Aug. 12, 1991; 57 FR 36014, Aug. 12, 1992; 61 FR 40345, Aug. 2, 1996]

§ 406.22 Effect of month of enrollment on entitlement.

(a) *Individual age 65 or over.* For an individual who has attained age 65, the following rules apply:

(1) If the individual enrolls during the 3 months before the first month of eligibility, entitlement begins with the first month of eligibility.

(2) If the individual enrolls in the first month of eligibility, entitlement begins with the following month.

(3) If the individual enrolls during the month after the first month of eligibility, entitlement begins with the second month after the month of enrollment.

(4) If the individual enrolls in either of the last 2 months of the enrollment period, entitlement begins with the third month after the month of enrollment.

(b) *Individual under age 65.* For an individual who has not attained age 65, the following rules apply:

(1) If the individual enrolls before the month in which he or she meets the requirements of § 406.20(c), entitlement begins with the month in which the individual meets those requirements.

(2) If the individual enrolls in the month in which he or she first meets the requirements of § 406.20(c), entitlement begins with the following month.

(3) If the individual enrolls in the month following the month in which he or she meets the requirements of § 406.20(c), entitlement begins with the second month after the month of enrollment.

(4) If the individual enrolls more than one month after the month in which he or she first meets the requirements of § 406.20(c), entitlement begins with the third month after the month of enrollment.

[56 FR 38079, Aug. 12, 1991]

§ 406.24 Special enrollment period.[1]

(a) *Terminology*. As used in this subpart, the following terms have the indicated meanings.

(1) *Current employment status* has the meaning given this term in § 411.104 of this chapter.

(2) *Family member* has the meaning given this term in § 411.201 of this chapter.

(3) *Group health plan (GHP)* and *large group health plan (LGHP)* have the meanings given those terms in § 411.101 of this chapter, except that the ''former employee'' language of those definitions does not apply with respect to SEPs because—

(i) Section 1837(i)(1)(A) of the Act explicitly requires that GHP coverage of an individual age 65 or older, be by reason of the individual's (or the individual's spouse's) current employment status; and

(ii) The sentence following section 1837(i)(1)(B), of the Act refers to ''large group health plan''. Under section 1862(b)(1)(B)(i), as amended by OBRA '93, LGHP coverage of a disabled individual must be ''by virtue of the individual's or a family member's current employment status with an employer''.

(4) *Special enrollment period (SEP)* is a period provided by statute to enable certain individuals to enroll in Medicare without having to wait for the general enrollment period.

(b) *Duration of SEP*.[2] (1) The SEP includes any month during any part of which—

(i) An individual over age 65 is enrolled in a GHP by reason of the current employment status of the individual or the individual's spouse; or

(ii) An individual under age 65 and disabled—

(A) Is enrolled in a GHP by reason of the current employment status of the individual or the individual's spouse; or

(B) Is enrolled in an LGHP by reason of the current employment status of the individual or a member of the individual's family.

(2) The SEP ends on the last day of the eighth consecutive month during which the individual is at no time enrolled in a GHP or an LGHP by reason of current employment status.

(c) *Conditions for use of a SEP*.[3] In order to use a SEP, the individual must meet the following conditions:

(1) When first eligible to enroll for premium hospital insurance under § 406.20(b) or (c), the individual was—

(i) Age 65 or over and covered under a GHP by reason of the current employment status of the individual or the individual's spouse;

(ii) Under age 65 and covered under an LGHP by reason of the current employment status of the individual or a member of the individual's family ; or

(iii) Under age 65 and covered under a GHP by reason of the current employment status of the individual or the individual's spouse.

(2) For all the months thereafter, the individual has maintained coverage either under hospital insurance or a GHP or LGHP.

(d) *Special rule: Additional SEPs*. (1) Generally, if an individual fails to enroll during any available SEP, he or she is not entitled to any additional SEPs.

(2) However, if an individual fails to enroll during a SEP, because coverage under the same or a different GHP or LGHP was restored before the end of that particular SEP, that failure to enroll does not preclude additional SEPs.

(e) *Effective date of coverage*. (1) If the individual enrolls in a month during any part of which he or she is covered under a GHP or LGHP on the basis of current employment status, or in the first full month when no longer so covered, coverage begins on the first day of the month of enrollment or, at the individual's option, on the first day of any of the three following months.

[1] Before August 1986, SEPs were available only for enrollment in supplementary medical insurance, not for enrollment in premium hospital insurance.

[2] Before March 1995, SEPs began on the first day of the first month the individual was no longer covered under a GHP or LGHP by reason of current employment status.

[3] Before August 10, 1993, an individual under age 65 could qualify for a SEP only if he or she had LGHP coverage as an ''active individual'', which the statute defined as ''an employee, employer, self-employed individual (such as the employer), individual associated with the employer in a business relationship, or as a member of the family of any of those persons''.

(2) If the individual enrolls in any month of the SEP other than the months specified in paragraph (e)(1) of this section, coverage begins on the first day of the month following the month of enrollment.

[61 FR 40346, Aug. 2, 1996]

§ 406.26 Enrollment under State buy-in.

(a) *Enrollment of QMBs under a State buy-in agreement*—(1) *Effective date*. Beginning with calendar year 1990, a State may request and be granted a modification of its buy-in agreement to include enrollment and payment of Part A premiums for QMBs (as defined in section 1905(p)(1) of the Act) who can become entitled to Medicare Part A only by paying a premium.

(2) *Amount of premium*. Premiums paid under State buy-in are not subject to increase because of late enrollment or reenrollment.

(b) *Beginning of coverage under buy-in*. The coverage period begins with the latest of the following:

(1) The third month following the month in which the agreement modification covering QMBs is effectuated.

(2) The first month in which the individual is entitled to premium hospital insurance under § 406.20(b) and has QMB status.

(3) The date specified in the agreement modification.

(c) *End of coverage under buy-in*. Buy-in coverage ends with the earlier of the following:

(1) *Death*. Coverage ends on the last day of the month in which the QMB dies.

(2) *Loss of QMB status*. If the individual loses eligibility for QMB status, coverage ends on the last day of the month in which CMS receives the State's notice of ineligibility.

(3) *Termination of buy-in agreement*. If the State's buy-in agreement is terminated, coverage ends on the last day of the last month for which the agreement is in effect.

(4) *Entitlement to premium-free Part A*. If the individual becomes entitled to premium-free Part A, buy-in coverage ends on the last day of entitlement to premium Part A.

(d) *Continuation of coverage: Individual enrollment following termination of buy-in coverage*—(1) *Deemed enrollment*. If coverage under a buy-in agreement ends because the agreement is terminated or the individual loses QMB status, the individual—

(i) Is considered to have enrolled during his or her initial enrollment period; and

(ii) Is entitled to Part A benefits and liable for Part A premiums beginning with the first month for which he or she is no longer covered under the buy-in agreement.

(2) *Voluntary termination*. (i) An individual may voluntarily terminate entitlement acquired under paragraph (d)(1) of this section by filing, with SSA or CMS, a request for disenrollment.

(ii) Voluntary disenrollment is effective as follows:

(A) If the individual files a request within 30 days after the date of CMS's notice that buy-in coverage has ended, the individual's entitlement ends on the last day of the last month for which the State paid the premium.

(B) If the individual files the request more than 30 days but not more than 6 months after buy-in coverage ends, entitlement ends on the last day of the month in which the request is filed.

(C) If the individual files the request later than the 6th month after buy-in coverage ends, entitlement ends at the end of the month after the month in which request is filed.

[56 FR 38080, Aug. 12, 1991]

§ 406.28 End of entitlement.

Any of the following actions or events ends entitlement to premium hospital insurance:

(a) *Filing of request for termination*. The beneficiary may at any time give CMS or the Social Security Administration written notice that he or she no longer wishes to participate in the premium hospital insurance program.

(1) If he or she files the notice before entitlement begins, he or she will be deemed not to have enrolled.

(2) If he or she files the notice after entitlement begins, that entitlement will end at the close of the month following the month in which he or she filed the notice.

(b) *Eligibility for hospital insurance without premiums*. (1) If an individual

meets the eligibility requirements for hospital insurance specified in § 406.10, § 406.11, § 406.13 or § 406.15, entitlement to premium hospital insurance ends with the month before the month in which he or she meets those requirements.

(2) If an individual meets the requirements of § 406.10, § 406.11, § 406.13, or § 406.15, he or she will be deemed to have filed the required application for hospital insurance benefits in his or her first month of eligibility under that section.

(c) *End of entitlement to supplementary medical insurance (SMI) for individual who has attained age 65.* In the case of an individual enrolled on the basis of § 406.20(b), entitlement to premium hospital insurance ends on the same date that entitlement to SMI ends.

(d) *Nonpayment of premium.* (1) If an individual fails to pay the premium bill, entitlement will end on the last day of the third month after the billing month.

(2) CMS may reinstate entitlement if the individual shows good cause for failure to pay on time, and pays all overdue premiums within 3 calendar months after the date specified in paragraph (d)(1) of this section.

(e) *Death.* Entitlement ends with the day of death. (A premium is due for the month of death.)

(f) *End of disabling impairment for individual under age 65.* In the case of an individual enrolled on the basis of § 406.20(c), entitlement to premium hospital insurance ends on the last day of the month after the month in which the individual is notified that he or she no longer has a disabling impairment.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 53 FR 47204, Nov. 22, 1988. Redesignated and amended at 56 FR 38080, Aug. 12, 1991]

§ 406.32 Monthly premiums.

(a) *Promulgation and effective date.* Beginning with 1984, premiums are promulgated each September, effective for the succeeding calendar year.

(b) *Monthly premiums: Determination of dollar amount.*

(1) Effective for calendar years beginning January 1989, the dollar amount is determined based on an estimate of one-twelfth of the average per capita costs for benefits and administrative costs that will be payable with respect to individuals age 65 or over from the Federal Hospital Insurance Trust Fund during the succeeding calendar year.

(2) Before 1989, the dollar amount was determined by multiplying $33 by the ratio of the next year's inpatient deductible to $76, which was the inpatient deductible determined for 1973. (Because of cost controls, the deductible actually charged for that year was $72.)

(3) Effective for months beginning January 1994, if an individual meets the requirements in paragraph (c) of this section, the monthly premium determined under paragraph (b)(1) of this section is reduced in each month in which the individual meets the requirements by 25 percent in 1994, 30 percent in 1995, 35 percent in 1996, 40 percent in 1997 and 45 percent in 1998 and thereafter.

(4) The amount determined under paragraphs (b) (1), (2), or (3) of this section is rounded to the next nearest multiple of $1. (Fifty cents is rounded to the next higher dollar.)

(c) *Qualifying for a reduction in monthly premium.* An individual who qualifies for the reduction described in paragraph (b)(3) of this section must be an individual who—

(1) Has 30 or more quarters of coverage (QCs) as defined in 20 CFR 404.140 through 404.146;

(2) Has been married for at least the previous one year period to a worker who has 30 or more QCs;

(3) Had been married to a worker who had 30 or more QCs for a period of at least one year before the death of the worker;

(4) Is divorced from, after at least 10 years of marriage to, a worker who had 30 or more QCs at the time the divorce became final; or

(5) Is divorced from, after at least 10 years of marriage to, a worker who subsequently died and who had 30 or more QCs at the time the divorce became final.

(d) *Monthly premiums: Increase for late enrollment and for reenrollment.* For an individual who enrolls after the close of the initial enrollment period or reenrolls, the amount of the monthly premium, as determined under paragraph (b) of this section, is increased

by 10 percent for each full 12 months in the periods described in §§ 406.33 and 406.34. Effective beginning with premiums due for July 1986, the premium increase is limited to 10 percent and is payable for twice the number of full 12-month periods determined under those sections.

(e) *Collection of monthly premiums.* (1) CMS will bill the enrollee on a monthly basis and include an addressed return envelope with the bill.

(2) The enrollee must pay by check or money order that is payable to ''CMS Medicare Insurance,'' and shows his or her name and the claim number that appears on his or her Medicare card. He or she must return the bill with the check or money order.

(f) *Months for which payment is due.* (1) A premium payment is due for each month beginning with the first month of coverage and continuing through the month of death or if earlier, the month in which coverage ends.

(2) A premium is due for the month of death if coverage is still in effect, even if the individual dies on the first day of the month.

(g) *Option for group payments.* A public or private organization may pay the premiums on behalf of one or more enrollees under a contract or other arrangement with CMS if CMS determines that this method of payment is administratively feasible. (The rules set forth in subpart E of part 408 of this chapter, for SMI premiums, also apply to group payment of Part A premiums.)

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 53 FR 47203, Nov. 22, 1988; 56 FR 8839, Mar. 1, 1991. Redesignated and amended at 56 FR 38079, 38080, Aug. 12, 1991; 57 FR 36014, Aug. 12, 1992; 57 FR 58717, Dec. 11, 1992; 59 FR 26959, May 25, 1994]

§ 406.33 Determination of months to be counted for premium increase: Enrollment.

(a) *Enrollment before April 1, 1981, or after September 30, 1981.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the end of the general enrollment period, the special enrollment period, or the transfer enrollment period in which the individual enrolls, excluding the following:

(1) Any months before September 1973.

(2) For premiums due for months after May 1986, any months beginning with January 1983 during which the individual was enrolled in an employer group health plan based on the current employment of the individual or the individual's spouse.

(3) Any months during the 7-month special enrollment period under § 406.21(e) during which premium hospital insurance coverage is in effect.

(4) Any months that the individual was enrolled in an HMO or CMP under part 417, subpart K of this chapter as described in § 406.21(f).

(b) *Enrollment during the period April 1 through September 30, 1981.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the month in which the individual enrolled, excluding any months before September 1973.

(c) *Examples.* (1) John F's initial enrollment period ended July 1979 but he did not enroll until January 1980. The months to be counted are August 1979 through March 1980. Since only 8 months elapsed, there is no premium increase.

(2) Mary T's initial enrollment period ended in April 1980 but she did not enroll until May 1981. The months to be counted are May 1980 through May 1981. Since 13 months has elapsed, the premium would be increased by 10 percent.

(3) Effective with July 1986, Mary T, in Example 2, would no longer have to pay an increased premium because she had paid it for twice the number of full 12-month periods during which she could have been, but was not, enrolled in the program.

(4) Vincent C's initial enrollment period ended August 31, 1986. He was covered under his wife's employer group health plan until she retired on May 31, 1989. He enrolled during June 1989, the first month of the special enrollment period under § 406.21(e). No months are countable for premium increase purposes because the exclusions of paragraph (a) of this section apply to all months.

(5) Terry P enrolled in the 1987 general enrollment period, with coverage effective July 1987. There were 28

months after the end of his initial enrollment period through the end of the 1987 general enrollment period. His premium is increased by 10 percent. The increase will be eliminated after he has paid the additional 10 percent for 48 months.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 53 FR 47203, Nov. 22, 1988. Further redesignated and amended at 57 FR 36014, Aug. 12, 1992]

§ 406.34 Determination of months to be counted for premium increase: Reenrollment.

(a) *First reenrollment before April 1, 1981 or after September 30, 1981.* The months to be counted for premium increase are:

(1) The months specified in § 406.33(a) or (b); plus

(2) The months from the end of the first period of entitlement through the end of the general enrollment period in which the individual reenrolled.

(b) *First reenrollment during the period April 1, 1981* through September 30, 1981. The months to be counted for premium increase are—

(1) The months specified in § 406.33(a); plus

(2) The months from the end of the first period of entitlement through the month in which the individual reenrolled.

(c) *Subsequent reenrollment during the period April 1, 1981 through September 30, 1981.* The months to be counted for premium increase are—

(1) The months specified in paragraph (a) of this section; plus

(2) The months from April 1981 through the month in which the individual reenrolled for the second time. (Since only one reenrollment was permitted before April 1981, any months from the end of the individual's first enrollment period of entitlement through March 1981 are not counted.)

(d) *Subsequent reenrollment after September 30, 1981.* The months to be counted for premium increase are—

(1) The months specified in paragraph (a) or (b) of this section, for the first and second periods of coverage; plus

(2) The months from the end of each subsequent period of entitlement through the end of the general enrollment period in which the individual reenrolled, excluding any months before April 1981.

(e) *Example.* Peter M enrolled during his initial enrollment period, terminated his first coverage period in August 1979 and reenrolled for the first time in January 1980. The 7 months to be counted (September 1979 through March, 1980) were not enough to require any increase in the premium. Peter terminated his second period of coverage in February 1981 and reenrolled for the second time in July 1981. Since the 4 months (April through July 1981), when added to the previous 7 months, bring the total to only 11 months, no premium increase is required.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986. Further redesignated and amended at 57 FR 58717, Dec. 11, 1992]

§ 406.38 Prejudice to enrollment rights because of Federal Government error.

(a) If an individual's enrollment or nonenrollment for premium hospital insurance is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal Government to act on its behalf, the Social Security Administration or CMS may take whatever action it determines is necessary to provide appropriate relief.

(b) The action may include—

(1) Designation of a special initial or general enrollment period;

(2) Designation of an entitlement period;

(3) Adjustment of premiums;

(4) Any combination of the actions specified in paragraph (b) (1) through (3) of this section; or

(5) Any other remedial action which may be necessary to correct or eliminate the effects of such error, misrepresentation, or inaction.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986. Further redesignated at 56 FR 38080, Aug. 12, 1991]

Subpart D—Special Circumstances That Affect Entitlement to Hospital Insurance

§ 406.50 Nonpayment of benefits on behalf of certain aliens.

(a) Hospital insurance benefit payments may not be made for services furnished to an alien in any month in which his or her monthly social security benefits are suspended (or would be suspended if he or she were entitled to those benefits) because the alien remains outside the United States for more than 6 months.

(b) Benefits will be payable beginning with services furnished in the first full calendar month the alien is back in the United States.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986. Further redesignated at 57 FR 58717, Dec. 11, 1992]

§ 406.52 Conviction of certain offenses.

(a) *Penalty that affects entitlement.* (1) If an individual is convicted of any of the crimes listed in § 406.11(c) (1) and (2), the court may impose, in addition to all other penalties, a penalty that affects entitlement to hospital insurance, beginning with the month of conviction.

(2) The additional penalty is that the individual's income (or the income of the insured individual on whose earnings record he or she became or seeks to become entitled) for the year of conviction and any previous year may not be counted in determining the insured status necessary for entitlement to hospital insurance.

(b) *Effect of pardon.* If the President of the United States pardons the convicted individual, that individual regains (or may again seek) entitlement effective with the month following the month in which the pardon is granted.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986. Further redesignated at 57 FR 58717, Dec. 11, 1992]

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 53 FR 47204, Nov. 22, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 407.1 Basis and scope.

(a) *Statutory basis.* The supplementary medical insurance (SMI) program is authorized by Part B of title XVIII of the Social Security Act.

(1) Section 1831 of the Act establishes the program.

(2) Sections 1836 and 1837 set forth the eligibility and enrollment requirements.

(3) Section 1838 specifies the entitlement periods, which vary depending on the time and method of enrollment and on the basis for termination.

(4) Section 1843 sets forth the requirements for State buy-in agreements under which States may enroll, and pay the SMI premiums for, eligible individuals who are also eligible for cash assistance or Medicaid.

(5) Section 104(b) of the Social Security Amendments of 1965 (Pub. L. 89–87) specifies the limitations that apply to certain aliens and persons convicted of subversive activities.

(b) *Scope.* This part sets forth the eligibility, enrollment, and entitlement requirements and procedures for supplementary medical insurance. (The rules about premiums are in part 408 of this chapter.)

§ 407.2 General description of program.

Part B of Title XVIII of the Act provides for voluntary ''supplementary medical insurance'' available to most individuals age 65 or over and to disabled individuals who are under age 65 and entitled to hospital insurance. The SMI program is financed by premiums paid by (or for) each individual enrolled in the program, plus contributions from Federal funds. It covers certain physicians' services, outpatient services, home health services, services furnished by rural health clinics (RHCs), Federally qualified health centers (FQHCS), ambulatory surgical centers (ASCs), and comprehensive outpatient rehabilitation facilities (CORFs), and other medical and other health services.

[57 FR 24980, June 12, 1992]

§ 407.4 Basic requirements for entitlement.

(a) An individual must meet the following requirements to be entitled to SMI:

(1) *Eligibility.* The individual must meet the eligibility requirements specified in § 407.10(a).

(2) *Enrollment.* The individual must enroll for SMI, or must be enrolled by a State under a buy-in agreement as specified in § 407.40.

(b) SMI pays only for covered expenses incurred during an individual's period of entitlement.

Subpart B—Individual Enrollment and Entitlement for SMI

§ 407.10 Eligibility to enroll.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, an individual is eligible to enroll for SMI if he or she—

(1) Is entitled to hospital insurance under any of the rules set forth in §§ 406.10 through 406.15 of this chapter; or

(2) Meets the following requirements:

(i) Has attained age 65. (An individual is considered to have attained age 65 on the day before the 65th anniversary of his or her birth.)

(ii) Is a resident of the United States.

(iii) Is a citizen of the United States, or an alien lawfully admitted for permanent residence who has resided continuously in the United States during the 5 years preceding the month in which he or she applies for enrollment.

(b) *Exception.* An individual is not eligible to enroll for SMI if he or she has been convicted of—

(1) Spying, sabotage, treason, or subversive activities under chapter 37, 105, or 115 of title 18 of the United States Code; or

(2) Conspiracy to establish dictatorship under section 4 of the Internal Security Act of 1950.

§ 407.11 Forms used to apply for enrollment under Medicare Part B.

The following forms, available free of charge by mail from CMS, or at any Social Security branch or district office, are used to apply for enrollment under the supplementary medical insurance program.

CMS–4040—Application for Enrollment in the Supplementary Medical Insurance Program. (This form is used for enrollment by individuals who are not eligible for monthly benefits or for hospital insurance.)

CMS–40–B—Application for Medical Insurance. (For general use by the SSA District Office in requesting medical insurance protection during the general enrollment period or during the initial enrollment period if the enrollee is not subject to automatic enrollment is SMI.)

CMS–40–D—Application for Enrollment in the Supplementary Medical Insurance Program. (This form is mailed to individuals who do not have current supplementary medical insurance because of prior refusals, voluntary withdrawal, or premium default from prior coverage. It is used during the annual general enrollment period.)

CMS–40–F—Application for Medical Insurance. (For use by beneficiaries residing outside the United States.)

CMS–18–F–5—Application for Hospital Insurance Entitlement. (For use by individuals who are not eligible for retirement benefits under Title II of the Social Security Act or under the Railroad Retirement Act. This form may also be used for enrollment in the supplementary medical insurance program.)

As an alternative, the individual may request enrollment by answering the Part B enrollment questions on an application for monthly Social Security benefits, or by signing a simple statement of request, if he or she is eligible to enroll at that time.

§ 407.12 General enrollment provisions.

(a) *Opportunity to enroll.* (1) An individual who is eligible to enroll for SMI may do so during an initial enrollment period or a general enrollment period as specified in §§ 407.14, and 407.15. An individual who meets the conditions specified in § 407.20 may enroll during a special enrollment period, as provided in that section.

(2) An individual who fails to enroll during his or her initial enrollment period or whose enrollment has been terminated may enroll or reenroll during a general enrollment period, or, if he or she meets the specified conditions, during a special enrollment period.

(b) *Enrollment periods ending on a nonworkday.* (1) If an enrollment period ends on a Federal nonworkday, that period is automatically extended to the next succeeding workday.

(2) A Federal nonworkday is any Saturday, Sunday, or Federal legal holiday or a day that is declared by statute or executive order to be a day on which Federal employees are not required to work.

§ 407.14 Initial enrollment period.

(a) *Duration.* (1) The initial enrollment period is the 7-month period that begins 3 months before the month an individual first meets the eligibility requirements of § 407.10 and ends 3 months after that first month of eligibility.

(2) In determining the initial enrollment period of an individual who is age 65 or over and eligible for enrollment solely because of entitlement to hospital insurance, the individual is considered as first meeting the eligibility requirements for SMI n the first day he or she becomes entitled to hospital insurance or would have been entitled if he or she filed an application for that program.

(b) *Deemed initial enrollment period.* (1) SSA or CMS will establish a deemed initial enrollment period for an individual who fails to enroll during the initial enrollment period because of a belief, based on erroneous documentary evidence, that he or she had not yet attained age 65. The period will be established as though the individual had attained age 65 on the date indicated by the incorrect information.

(2) A deemed initial enrollment period established under paragraph (b)(1) of this section is used to determine the individual's premium and right to enroll in a general enrollment period if that is advantageous to the individual.

§ 407.15 General enrollment period.

(a) Except as specified in paragraph (b) of this section, the general enrollment period is January through March of each calendar year.

(b) An unlimited general enrollment period existed between April 1 and September 30, 1981. Any eligible individual whose initial enrollment period had ended, or whose previous period of entitlement had terminated, could have enrolled or reenrolled during any month of that 6-month period.

§ 407.17 Automatic enrollment.

(a) *Who is automatically enrolled.* An individual is automatically enrolled for SMI if he or she:

(1) Resides in the United States, except in Puerto Rico;

(2) Becomes entitled to hospital insurance under any of the provisions set forth in §§ 406.10 through 406.15 of this chapter; and

(3) Does not decline SMI enrollment.

(b) *Opportunity to decline automatic enrollment.* (1) SSA will notify an individual that he or she is automatically enrolled under paragraph (a) of this section and grant the individual a specified period (at least 2 months after the month the notice is mailed) to decline enrollment.

(2) The individual may decline enrollment by submitting to SSA or CMS a signed statement that he or she does not wish SMI.

(3) The statement must be submitted before entitlement begins, or if later, within the time limits set in the notice of enrollment.

§ 407.18 Determining month of automatic enrollment.

(a) An individual who is automatically enrolled in SMI under § 407.17 will have the month of enrollment determined in accordance with paragraphs (b) through (f) of this section. The month of enrollment determines the month of entitlement.

(b) An individual is automatically enrolled in the third month of the initial enrollment period if he or she—

(1) Is entitled to social security benefits under section 202 of the Act on the first day of the initial enrollment period;

(2) Is entitled to hospital insurance based on end-stage renal disease; on entitlement to disability benefits as a social security or railroad retirement beneficiary; or on deemed entitlement to disability benefits on the basis of Medicare-qualified government employment; or

(3) Establishes entitlement to hospital insurance by filing an application and meeting all other requirements (as set forth in subpart B of part 406 of this chapter) during the first 3 months of the initial enrollment period.

(c) If an individual establishes entitlement to hospital insurance on the basis of an application filed in the last 4 months of the SMI initial enrollment period, he or she is automatically enrolled for SMI in the month in which the application is filed.

(d) If an individual establishes entitlement to hospital insurance on the basis of an application filed after the SMI initial enrollment period but not during a general enrollment period in effect before April 1, 1981, or after September 30, 1981, he or she is automatically enrolled for SMI on the first day of the next general enrollment period.

(e) If the individual establishes entitlement to hospital insurance on the basis of an application filed during a SMI general enrollment period in effect before April 1, 1981 or after September 30, 1981, he or she is automatically enrolled on the first day of that period.

(f) If an individual established entitlement to hospital insurance on the basis of an application filed during the general enrollment period of April 1, 1981, through September 30, 1981, he or she was automatically enrolled for SMI on the first day of the month in which the application was filed.

§ 407.20 Special enrollment period related to coverage under group health plans.

(a) *Terminology*—(1) *Group health plan (GHP) and large group health plan (LGHP).* These terms have the meanings given them in § 411.101 of this chapter except that the ''former employee'' language of those definitions does not apply with respect to SEPs for the reasons specified in § 406.24(a)(3) of this chapter.

(2) *Special enrollment period (SEP).* This term has the meaning set forth in § 406.24(a)(4) of this chapter. In order to use a SEP, an individual must meet the conditions of paragraph (b) and of paragraph (c) or (d) of this section, as appropriate.

(b) *General rule.* All individuals must meet the following conditions:

(1) They are eligible to enroll for SMI on the basis of age or disability, but not on the basis of end-stage renal disease.

(2) When first eligible for SMI coverage (4th month of their initial enrollment period), they were covered under a GHP or LGHP on the basis of current employment status or, if not so covered, they enrolled in SMI during their initial enrollment period; and

(3) For all months thereafter, they maintained coverage under either SMI or a GHP or LGHP. (Generally, if an individual fails to enroll in SMI during any available SEP, he or she is not entitled to any additional SEPs. However, if an individual fails to enroll during a SEP because coverage under the same or a different GHP or LGHP was restored before the end of that particular SEP, that failure to enroll does not preclude additional SEPs.)

(c) *Special rule: Individual age 65 or over*. For an individual who is or was covered under a GHP, coverage must be by reason of the current employment status of the individual or the individual's spouse.

(d) *Special rules: Disabled individual*.[4] Individuals entitled on the basis of disability (but not on the basis of end-stage renal disease) must meet conditions that vary depending on whether they were covered under a GHP or an LGHP.

(1) For a disabled individual who is or was covered under a GHP, coverage must be on the basis of the current employment status of the individual or the individual's spouse.

(2) For a disabled individual who is or was covered under an LGHP, coverage must be as follows:

(i) Before August 10, 1993, as an ''active individual'', that is, as an employee, employer, self-employed individual (such as the employer), individual associated with the employer in a business relationship, or as a member of the family of any of those persons.

(ii) On or after August 10, 1993, by reason of current employment status of the individual or a member of the individual's family.

[4] Under the current statute, the SEP provision applicable to disabled individuals covered under an LGHP expires on September 1998. Unless Congress changes that date, the last SEP available under those provisions will begin with June 1998.

(e) *Effective date of coverage*. The rule set forth in § 406.24(d) for Medicare Part A applies equally to Medicare Part B.

[61 FR 40346, Aug. 2, 1996]

§ 407.22 Request for individual enrollment.

(a) A request for enrollment is required of an individual who meets the eligibility requirements of § 407.10 and desires SMI, if the individual—

(1) Is not entitled to hospital insurance;

(2) Has previously declined enrollment in SMI;

(3) Has had a previous period of SMI entitlement which terminated;

(4) Resides in Puerto Rico or outside the United States; or

(5) Is enrolling or reenrolling during a special enrollment period under § 407.20.

(b) A request for enrollment under paragraph (a) of this section must:

(1) Be signed by the individual or someone acting in his or her behalf; and

(2) Be filed with SSA or CMS during the initial enrollment period, a general enrollment period, or a special enrollment period as provided in § 407.20.

§ 407.25 Beginning of entitlement: Individual enrollment.

The following apply whether an individual is self-enrolled or automatically enrolled in SMI:

(a) *Enrollment during initial enrollment period*. (1) If an individual enrolls during the first three months of the initial enrollment period, entitlement begins with the first month of eligibility.

(2) If an individual enrolls during the fourth month of the initial enrollment period, entitlement begins with the following month.

(3) If an individual enrolls during the fifth month of the initial enrollment period, entitlement begins with the second month after the month of enrollment.

(4) If an individual enrolls in either of the last two months of the initial enrollment period, entitlement begins with the third month after the month of enrollment.

(5) Example. An individual first meets the eligibility requirements for

enrollment in April. The initial enrollment period is January through July. The month in which the individual enrolls determines the month that begins the period of entitlement, as follows:

Enrolls in initial enrollment period	Entitlement begins on—
January	April 1 (month eligibility requirements first met).
February	April 1.
March	April 1.
April	May 1 (month following month of enrollment).
May	July 1 (second month after month of enrollment).
June	September 1 (third month after month of enrollment).
July	October 1 (third month after month of enrollment).

(b) *Enrollment on reenrollment during general enrollment period.* (1) if an individual enrolls or reenrolls during a general enrollment period before April 1, 1981 or after September 30, 1981, entitlement begins on July 1 of that calendar year.

(2) If an individual enrolled or reenrolled during the general enrollment period between April 1, 1981 and September 20, 1981, entitlement began with the third month after the month in which the enrollment request was filed.

(c) *Enrollment or reenrollment during a SEP.* The rules set forth in § 406.24(d) of this chapter apply.

[53 FR 47204, Nov. 22, 1988, as amended at 61 FR 40347, Aug. 2, 1996]

§ 407.27 Termination of entitlement: Individual enrollment.

An individual's entitlement will terminate for any of the following reasons:

(a) *Death.* Entitlement to SMI ends on the last day of the month in which the individual dies.

(b) *Termination of hospital insurance benefits.* If an individual's entitlement to hospital insurance ends before the month in which he or she attains age 65, entitlement to SMI will end on the same day unless it has been previously terminated in accordance with paragraph (c) or (d) of this section.

(c) *Request by individual.* An individual may at any time give CMS or SSA written notice that he or she no longer wishes to participate in SMI, and request disenrollment.

(1) Before July 1987, entitlement ended at the end of the calendar quarter after the quarter in which the individual filed the disenrollment request.

(2) For disenrollment requests filed in or after July 1987, entitlement ends at the end of the month after the month in which the individual files the disenrollment request.

(d) *Nonpayment of premiums.* If an individual fails to pay the premiums, entitlement will end as provided in the rules for SMI premiums, set forth in part 408 of this chapter.

§ 407.30 Limitations on enrollment.

(a) *Initial enrollment periods*—(1) *Individual under age 65.* An individual who has not attained age 65 may have one or more periods of entitlement to hospital insurance, based on disability. Since each period of disability entitlement entitles the individual to hospital insurance and since entitlement to hospital insurance makes the individual eligible for SMI enrollment, an individual may have an SMI initial enrollment period for each continous period of entitlement to hospital insurance.

(2) *Individuals who have attained age 65.* An individual who has attained age 65 may not have more than one initial enrollment period on the basis of age. However, if the individual develops ESRD after age 65, he or she may have another initial enrollment period based on meeting the requirements of § 406.13 of this chapter.

(b) *Number of enrollments.* There is no limitation on the number of enrollments.

(c) *Coverage under buy-in agreements.* For purposes of paragraph (a) of this section, the continued enrollment of an individual following the end of coverage under a State buy-in agreement in considered an initial enrollment.

§ 407.32 Prejudice to enrollment rights because of Federal Government misrepresentation, inaction, or error.

If an individual's enrollment or nonenrollment in SMI is unintentional, inadvertent, or erroneous because of the error, misrepresentation, on inaction of a Federal employee or any person authorized by the Federal Government to act in its behalf, the Social Security

Administration or CMS may take whatever action it determines is necessary to provide appropriate relief. The action may include:

(a) Designation of a special initial or general enrollment period;

(b) Designation of an entitlement period based on that enrollment period;

(c) Adjustment of premiums;

(d) Any combination of actions under paragraphs (a) through (c) of this section; or

(e) Any other remedial action that may be necessary to correct or eliminate the effects of the error, misrepresentation, or inaction.

Subpart C—State Buy-In Agreements

§ 407.40 Enrollment under a State buy-in agreement.

(a) *Statutory basis.* (1) Section 1843 of the Act, as amended through 1969, permitted a State to enter into an agreement with the Secretary to enroll in the SMI program certain individuals who are eligible for SMI and who are members of the buy-in group specified in the agreement. A buy-in group could include certain individuals receiving Federally-aided State cash assistance (with the option of excluding individuals also entitled to social security benefits or railroad retirement benefits) or could include all individuals eligible for Medicaid. Before 1981, December 31, 1969 was the last day on which a State could request a buy-in agreement or a modification to include a coverage group broader than the one originally selected.

(2) Section 945(e) of the Omnibus Reconciliation Act of 1980 (Pub. L. 96–499) further amended section 1843 to provide that, during calendar year 1981, a State could request a buy-in agreement if it did not already have one, or request a broader coverage group for an existing agreement.

(3) Several laws enacted during 1980–1987 had the effect of requiring that the buy-in groups available under section 1843 of the Act be expanded to include certain individuals who lose eligibility for cash assistance payments but are treated as if they were cash assistance recipients for Medicaid eligibility purposes.

(4) Section 301(e)(1) of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360) amends section 1843 of the Act to restore the 1981 provisions on a permanent basis, effective ''after 1988.''

(5) The same section 301, as amended by section 608(d)(14)(H) of the Family Support Act of 1988 (Pub. L. 100–485), further amended section 1843 of the Act, beginning January 1, 1989, to establish a new buy-in category consisting of Qualified Medicare Beneficiaries and to provide that a State may request a buy-in agreement if it does not already have one, or request a broader buy-in group for the existing agreement.

(b) *Definitions.* As used in this section, unless the context indicates otherwise—

Cash assistance means any of the following kinds of monthly cash benefits, authorized by specified titles of the Act and, for convenience, represented by initials, as follows:

AABD stands for aid to the aged, blind or disabled under the first title XVI of the Act in effect until December 31, 1973.

AB stands for aid to the blind under title X of the Act.

AFDC stands for aid to families with dependent children under Part A of title IV of the Act.

APTD stands for aid to the permanently and totally disabled under title XIV of the Act.

OAA stands for old-age assistance under title I of the Act.

SSI stands for supplemental security income for the aged, blind, and disabled under the second title XVI of the Act, effective January 1, 1974.

SSP stands for State supplementary payments, whether mandatory or optional, to an aged, blind, or disabled individual under the second title XVI or the Act.

Qualified Medicare Beneficiary or *QMB* means an individual who meets the definition in § 400.200 of this chapter and, therefore, is eligible to have the State Medicaid agency pay Medicare cost sharing amounts on his or her behalf.

Railroad retirement beneficiary means an individual entitled to receive an annuity under the Railroad Retirement Act of 1974.

State means one of the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, American Samoa, or the Northern Mariana Islands, except when reference is made to ''the 50 States''.

State buy-in agreement or *buy-in agreement* means an agreement authorized by section 1843 of the Act, under which a State secures SMI or premium HI coverage for individuals who are members of the buy-in group specified in the agreement, by enrolling them and paying the premiums on their behalf.

(c) *Basic rules.*

(1) A State that has a buy-in agreement in effect must enroll any individual who is eligible to enroll in SMI under § 407.10.

(2) Any State that does not have a buy-in agreement in effect may request buy-in for any one of the groups specified in §§ 407.42 and 407.43.

(3) Any State that does have an agreement may request a modification to cover a broader buy-in group or cancel its current agreement and request a new agreement to cover a narrower group.

[56 FR 38080, Aug. 12, 1991; 56 FR 50058, Oct. 3, 1991]

§ 407.42 Buy-in groups available to the 50 States, the District of Columbia, and the Northern Mariana Islands.

(a) *Categories included in the buy-in groups.* The buy-in groups that are available to the 50 States, the District of Columbia, and the Northern Mariana Islands are specified in paragraph (b) of this section in terms of the following categories:

(1) *Category A:* Individuals who—

(i) Receive SSI or SSP or both; and

(ii) Are covered under the State's Medicaid plan as categorically needy.

(2) *Category B:* Individuals who—

(i) Under the Act or any other provision of Federal law are treated, for Medicaid eligibility purposes, as though they were receiving SSI or SSP; and

(ii) Are covered under the State's Medicaid plan as categorically needy.

(3) *Category C:* Individuals who are receiving AFDC.

(4) *Category D:* Individuals who, under the Act or any other provision of Federal law, are treated, for Medicaid eligibility purposes, as though they were receiving AFDC.

(5) *Category E:* Individuals who, in accordance with § 435.114 or § 435.134 of this chapter, are covered under the State's Medicaid plan despite the increase in social security benefits provided by Public Law 92–336.

(6) *Category F:* Individuals who are Qualified Medicare Beneficiaries.[1]

(7) *Category G:* All other individuals who are eligible for Medicaid.

(b) *Buy-in groups available.* Any of the 50 States, the District of Columbia, and the Northern Mariana Islands may buy-in for one of the following groups:

(1) *Group 1:* Categories A through G.

(2) *Group 2:* Categories A through F.

(3) *Group 3:* Categories A through E.

(4) *Group 4:* Categories A, B, and F, individuals in categories C and D who are not social security or railroad retirement beneficiaries, and individuals in category E who are included in that category (in accordance with § 435.134 of this chapter) because they received OAA, AB, APTD, or AABD in August 1972 or would have been eligible to receive such cash assistance for that month if they had applied or had not been institutionalized.

(5) *Group 5:* Categories A and B, individuals in categories C and D who are not social security or railroad retirement beneficiaries, and individuals in category E who are included in that category (in accordance with § 435.134 of this chapter) because they received OAA, AB, APTD, or AABD in August 1972 or would have been eligible to receive such cash assistance for that month if they had applied or had not been institutionalized.

(6) *Group 6:* Categories A, B, and F, and individuals in category E who are included in that category (in accordance with § 435.134 of this chapter) because they received AABD in August 1972 or would have been eligible to receive AABD for that month if they had applied or had not been institutionalized. This option is available only to those States that had an AABD program as of December 31, 1973.

[1] Rules for buy-in for premium hospital insurance for QMBs are set forth in § 406.26 of this chapter.

(7) *Group 7:* Categories A and B, and individuals in category E who are included in that category (in accordance with § 435.134 of this chapter) because they received AABD in August 1972 or would have been eligible to receive AABD for that month if they had applied or had not been institutionalized. This option is available only to those States that had an AABD program as of December 31, 1973.

[56 FR 38081, Aug. 12, 1991]

§ 407.43 Buy-in groups available to Puerto Rico, Guam, the Virgin Islands, and American Samoa.

(a) *Categories included in buy-in groups.* The buy-in groups that are available to Puerto Rico, Guam, the Virgin Islands, and American Samoa, which are not covered by the SSI program, are described in paragraph (b) of this section in terms of the following categories:

(1) *Category A:* Individuals receiving OAA, AB, APTD, or AFDC.

(2) *Category B:* Individuals who, under the Act or any other provision of Federal law, are treated, for Medicaid eligibility purposes, as though they were receiving AFDC.

(3) *Category C:* Individuals who, in accordance with § 436.112 of this chapter, are covered under the State's Medicaid plan despite the increase in social security benefits provided by Public Law 92–336.

(4) *Category D:* Individuals who are Qualified Medicare Beneficiaries.[1]

(5) *Category E:* All other individuals who are eligible for Medicaid.

(b) *Buy-in groups available.* Puerto Rico, Guam, the Virgin Islands, and American Samoa may choose any of the following coverage groups:

(1) *Group 1:* Categories A through E.

(2) *Group 2:* Categories A through D.

(3) *Group 3:* Categories A through C.

(4) *Group 4:* Individuals in category D, and individuals in categories A and B who are not social security or railroad retirement beneficiaries.

(5) *Group 5:* Individuals in categories A and B who are not social security or railroad retirement beneficiaries.

(6) *Group 6:* Individuals in category D, individuals in category A who are receiving OAA, and individuals in category C who are included in that category (in accordance with § 436.112 of this chapter) because they received OAA for August 1972 or would have been eligible to receive OAA for that month if they had applied or had not been institutionalized.

(7) *Group 7:* Individuals in category A who are receiving OAA, and individuals in category C who are included in that category (in accordance with § 436.112 of this chapter) because they received OAA for August 1972 or would have been eligible to receive OAA for that month if they had applied or had not been institutionalized.

(8) *Group 8:* Individuals in category D and individuals in category A who are receiving OAA and are not social security or railroad retirement beneficiaries.

(9) *Group 9:* Individuals in category A who are receiving OAA and are not social security or railroad retirement beneficiaries.

[56 FR 38082, Aug. 12, 1991]

§ 407.45 Termination of State buy-in agreements.

(a) *Termination by the State*—(1) *Termination after advance notice.* A State may terminate its buy-in agreement after giving CMS 3 months, advance notice.

(2) *Termination without advance notice.* A State may terminate its buy-in agreement without advance notice if—

(i) The State gives CMS written certification to the effect that it is no longer legally able to comply with one or more of the provisions of the agreement; and

(ii) Submits a supporting opinion from the appropriate State legal officer, if CMS requests such an opinion.

(b) *Termination by CMS.* If CMS, after giving the State notice and opportunity for hearing, finds that the State has failed to comply substantially with one or more of the provisions of the agreement, other than the requirement for timely payment of premiums, CMS will give the State written notice to the effect that the agreement will terminate on the date indicated in the notice unless, before that date, CMS finds that there is no longer that failure to

[1] Rules for buy-in for premium hospital insurance for QMBs are set forth in § 406.26 of this chapter.

comply. (Rules for collection of overdue premiums, including assessment of interest and offset against FFP due the State, are those set forth in the Notice published on September 30, 1985 at 50 FR 39784.)

§ 407.47 Beginning of coverage under a State buy-in agreement.

(a) *General rule.* The beginning of an individual's coverage period depends on two factors:

(1) The individual's meeting the SMI eligibility requirements and the requirements for being a member of the buy-in group; and

(2) The effective date of the buy-in agreement or agreement modification that covers the group to which the individual belongs, and which may not be earlier than the third month after the month in which the agreement or modification is executed.

(b) *Application of general rule: Medicaid eligibles who are, or are treated as, cash assistance recipients.* For Medicaid eligibles who are, or are treated as, cash assistance recipients (that is, are members of categories A through E of § 407.42(a) or categories A through C of § 407.43(a)), coverage begins with the later of the following:

(1) The first month in which the individual—

(i) Meets the SMI eligibility requirements specified in § 407.10; and

(ii) Is a member of one of those categories.

(2) The month in which the buy-in agreement is effective.

(c) *Application of general rule: Qualified Medicare Beneficiaries.* For individuals who are QMBs (that is, are members of category F of § 407.42 or category D of § 407.43(a)), coverage begins with the later of the following:

(1) The first month in which the individual meets the SMI eligibility requirements specified in § 407.10, and has QMB status.

(2) The month in which the buy-in agreement or agreement modification covering QMBs is effective.

(d) *Application of general rule: Other individuals eligible for Medicaid.* For individuals who are members of category G of § 407.42(a) or category E of § 407.43(a), coverage begins with the later of the following:

(1) The second month after the month in which the individual—

(i) Meets the SMI eligibility requirements specified in § 407.10; and

(ii) Is determined to be eligible for Medicaid.

(2) The month in which the buy-in agreement or agreement modification is effective.

(e) *Coverage based on erroneous report.* If the State erroneously reports to SSA that an individual is a member of its coverage group, the rules of paragraphs (a) through (d) of this section apply, and coverage begins as though the individual were in fact a member of the group. Coverage will end only as provided in § 407.48.

[56 FR 38082, Aug. 12, 1991]

§ 407.48 Termination of coverage under a State buy-in agreement.

An individual's coverage under a buy-in agreement terminates with the earliest of the following events:

(a) *Death.* Coverage ends on the last day of the month in which the individual dies.

(b) *Loss of entitlement to hospital insurance benefits before age 65.* If an individual loses entitlement to hospital insurance benefits before attaining age 65, coverage ends on the last day of the last month for which he or she is entitled to hospital insurance.

(c) *Loss of eligibility for the buy-in group.* If an individual loses eligibility for inclusion in the buy-in group, buy-in coverage ends as follows:

(1) On the last day of the last month for which he or she is eligible for inclusion in the group, if CMS determines ineligibility or receives a State ineligibility notice by the 25th day of the second month after the month in which the individual becomes ineligible for inclusion in the group.

(2) On the last day of the second month before the month in which CMS receives a State ineligibility notice later than the time specified in paragraph (c)(1) of this section. A notice received by CMS after the 25th day of the month is considered to have been received in the following month.

(d) *Termination or modification of buy-in agreement.* If the State's buy-in agreement is terminated, or modified to substitute a narrower buy-in group,

coverage ends on the last day of the last month for which the agreement was in effect, or covered the broader buy-in group.

[53 FR 47204, Nov. 22, 1988, as amended at 56 FR 38082, Aug. 12, 1991]

§ 407.50 Continuation of coverage: Individual enrollment following end of coverage under a State buy-in agreement.

(a) *Deemed enrollment.* When coverage under a buy-in agreement ends because the agreement terminates, or is modified to substitute a narrower buy-in group, or because the individual is no longer eligible for inclusion in the buy-in group, the individual—

(1) Is considered to have enrolled during his or her initial enrollment period; and

(2) Will be entitled to SMI on this basis and liable for SMI premiums beginning with the first month for which he or she is no longer covered under the buy-in agreement.

(b) *Voluntary termination.* (1) An individual may voluntarily terminate entitlement acquired under paragraph (a) of this section by filing, with SSA or CMS, a request for disenrollment.

(2) Voluntary disenrollment is effective as follows:

(i) If the individual files a request within 30 days after the date of CMS's notice that buy-in coverage has ended, the individual's entitlement ends on the last day of the last month for which the State paid the premium.

(ii) If the individual files the request more than 30 days but not more than 6 months after buy-in coverage ends, entitlement ends on the last day of the month in which the request is filed.

(iii) If the individual files the request later than the 6th month after buy-in coverage ends, entitlement ends at the end of the month after the month in which request is filed.[1]

[53 FR 47204, Nov. 22, 1988, as amended at 56 FR 38082, Aug. 12, 1991]

[1] For requests filed before July 1987, entitlement ended on the last day of the calendar quarter after the quarter in which the disenrollment request was filed.

PART 408—PREMIUMS FOR SUPPLEMENTARY MEDICAL INSURANCE

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 52 FR 48115, Dec. 18, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 408.1 Statutory basis.

(a) This part implements certain provisions of sections 1837 through 1840 and 1881(d) of the Social Security Act (the Act) and conforms to other regulations that implement section 1843 of the Act. Section 1838(b) requires regulations to establish when an individual's coverage ends because of nonpayment of premiums. It also specifies that those regulations may provide a grace period for payment of overdue premiums without loss of coverage. Section 1839 sets forth the specific procedures for determining the amount of the monthly premium and section 1840 establishes the rules for payment of premiums. Section 1843 provides that a State may enter into a buy-in agreement to secure SMI coverage for certain individuals by enrolling them in the SMI program and paying the premiums on their behalf. Section 1881(d) provides that Medicare payment, for the reasonable charges incurred in connection with a kidney donation, shall be made (without regard to deductible, premium, or coinsurance provisions of title XVIII) as prescribed in regulations.

(b) The Federal Claims Collection Act (31 U.S.C. 3711), as implemented by 4 CFR parts 101–105, provides the basic authority for recovery of debts owed the United States government and specifies the conditions for the suspension or termination of collection action. Departmental regulations at 45 CFR part 30, updated by a final rule published on January 5, 1987 (52 FR 260) set forth procedures for the exercise of the Department's authority to collect and dispose of debts and were intended to complement rules applicable to particular programs. CMS rules are set forth at 42 CFR part 401, subpart F.

[52 FR 48115, Dec. 18, 1987; 53 FR 4158, Feb. 12, 1988, as amended at 56 FR 48112, Sept. 24, 1991]

§ 408.2 Scope and purpose.

(a) This part sets forth the policies and procedures for determining the amount of monthly supplementary medical insurance (SMI) premiums, for the payment, collection, or refund of premiums, for termination of coverage because of nonpayment of premiums, and for reinstatement of coverage if certain conditions are met. It conforms to subpart C of part 407 of this chapter, which sets forth the requirements for State buy-in agreements. These policies are intended to protect enrollee coverage to the maximum degree compatible with maintaining the integrity of the SMI program.

(b) Policies that apply to premiums that certain individuals must pay in order to become entitled to Medicare Part A hospital insurance benefits, are set forth in part 406 of this chapter.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

§ 408.3 Definitions.

As used in this part, unless the context indicates otherwise—

Enrollee means an individual who is enrolled in the SMI program under Medicare Part B.

Taxable year means the 12-month period (calendar or fiscal year) for which the individual files his or her income tax return.

§ 408.4 Payment obligations.

(a) *Month for which payment is due.* (1) A payment is due for each month, beginning with the first month of SMI coverage and continuing through the month of death or, if earlier, the month in which coverage terminates.

(2) A premium is due for the month of death, if SMI coverage is still in effect, even though the individual dies on the first day of the month.

(b) *Overdue premiums.* (1) Overdue premiums constitute an obligation enforceable against the enrollee or the enrollee's estate.

(2) Overdue premiums are collected—

(i) By deduction from social security or railroad retirement benefits or Federal civil service annuities;

(ii) Directly from the enrollee or the enrollee's estate; or

(iii) By offset against any SMI payments payable to the enrollee or the enrollee's estate.

(3) Interest is not charged on overdue premiums, except under a State buy-in agreement, as provided in § 408.6(c)(4).

(c) *Premiums not required for certain kidney donors.* (1) No premiums are required for SMI benefits related to the donation of a kidney if the donor is not an enrollee.

(2) A kidney donor who is an enrollee is not relieved of the obligation for premiums.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

§ 408.6 Methods and priorities for payment.

(a) *Methods of payment*—(1) *General rules.* Premiums are paid by one of the following four methods:

(i) Payment by a State under a buy-in agreement.

(ii) Deduction from monthly railroad retirement of social security cash benefits or Federal civil service annuities.

(iii) Direct remittance on an individual basis, by or on behalf of the enrollee.

(iv) Direct remittance on a group basis, by an employer, union, lodge or other organization, or by an entity of State or local government.

(2) *Special situations.* (i) If the monthly social security benefit or age 72 special benefit is less than the monthly premium, the benefit is withheld and the enrollee is required to pay the balance through direct remittance. (This situation may arise if the individual first becomes eligible for social security benefits after December 31, 1981, and is, therefore, not eligible for the fixed minimum, or receives age 72 special benefits that are reduced because the individual receives a government pension.)

(ii) If the monthly railroad retirement benefit or civil service annuity payment is less than the premium, the monthly payment is not withheld and the enrollee is required to pay the total premium by direct remittance.

(b) *Priorities for payment.* (1) If an enrollee is enrolled under a State buy-in agreement—

(i) SMI premiums may not be deducted from monthly cash benefits or annuities; and

(ii) The enrollee may not be required to pay by direct remittance.

(2) If an enrollee is not covered under a State buy-in agreement, but is receiving a monthly benefit or an annuity specified in paragraph (a)(1)(ii) of this section—

(i) The premiums are deducted from that benefit or annuity; or

(ii) If the monthly benefit or payment is less than the monthly premium, the rules of paragraph (a)(2) of this section apply.

(3) If an enrollee is neither covered under a State buy-in agreement, nor receiving monthly benefits or annuity payments, the premiums must be paid totally by direct remittance.

(c) *Payment by a State under a buy-in agreement.* (1) A buy-in agreement is an agreement under which a State, through enrollment and payment of SMI premiums, secures SMI benefits

for individuals who are eligible for that program and also eligible for certain other cash or medical benefits. (Policies on enrollment under State buy-in agreements are contained in subpart C of part 407 of this chapter.)

(2) The State pays the premiums for each month for which an individual is covered under the agreement.

(3) If an individual's coverage under a State buy-in agreement terminates, his coverage continues on an individual enrollment basis. The premiums are then deducted from benefits, as set forth in subpart C of this part, or paid by direct remittance in accordance with subpart D or subpart E of this part.

(4) Policy on collection of premiums from buy-in States is set forth in a FEDERAL REGISTER notice published on September 30, 1985 at 50 FR 39784.

§ 408.8 Grace period and termination date.

(a) *Grace period*. (1) For all initial premium payments (monthly or quarterly), and subsequent monthly or quarterly payments, the grace period ends with the last day of the third month after the billing month.

(2) For payments required because the monthly benefit is less than the monthly premium, the grace period ends on April 30 of the year following the calendar year which the premiums are due.

(b) *Extension of grace period: Last day is nonwork day*. If the last day of the grace period is a Saturday, Sunday, legal holiday, or a day that, by statute or executive order, is a nonwork day for Federal employees, the grace period is extended to the next succeeding work day.

(c) *Termination date*. The end of the grace period is the termination date for SMI coverage if overdue premiums have not been paid by that date in accordance with § 408.68.

(d) *Extension of grace period for good cause*. (1) CMS may reinstate entitlement, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within three calendar months after the termination date.

(2) Good cause will be found if the individual establishes, by a credible statement, that failure to pay premiums within the initial grace period was due to conditions over which he or she had no control, or which he or she could not reasonably have been expected to foresee.

[52 FR 48115, Dec. 18, 1987, as amended at 56 FR 48112, Sept. 24, 1991]

§ 408.10 Claim for monthly benefits pending concurrently with request for SMI enrollment.

(a) If it is clear that an individual who applies for social security or railroad retirement benefits and for SMI will be entitled to monthly benefits, the application for monthly benefits is processed simultaneously with the request for SMI enrollment.

(1) If monthly benefits are paid, the SMI premiums are deducted from those benefits.

(2) If monthly benefits are suspended (for instance, because the individual's earnings exceed the maximum allowed by law), the enrollee is billed for direct remittance.

(b) If it is clear that an individual will be entitled to SMI, but there is substantial question as to eligibility for monthly benefits, the request for SMI enrollment is processed separately.

(1) When SMI enrollment is approved, the enrollee is billed for direct remittance.

(2) When the application for monthly benefits is adjudicated, the following rules apply:

(i) If monthly benefits are paid, the SMI premiums are deducted from those benefits, with appropriate adjustments for any premiums already paid by direct remittance.

(ii) If the application for monthly benefits is approved but the benefits are suspended, the grace period is as set forth in § 408.8(a).

(iii) If the application for monthly benefits is denied, the grace period is as set forth in § 408.8(a)(1).

[52 FR 48115, Dec. 18, 1987, as amended at 56 FR 48112, Sept. 24, 1991]

Subpart B—Amount of Monthly Premiums

§ 408.20 Monthly premiums.

(a) *Statutory provisions.* (1) The law established a monthly premium of $3 for the initial period of the program. It also set forth criteria and procedures for the Secretary to follow each December, beginning with December 1968, to determine and promulgate the standard monthly premium for the 12–month period beginning with July of the following year.

(2) The law was amended in 1983 to require that the Secretary promulgate the standard monthly premium in September of that year, and each year thereafter, to be effective for the 12 months beginning with the following January.

(3) The standard monthly premium applies to individuals who enroll during their initial enrollment periods. In other situations, that premium may be increased or decreased as specified in this subpart.

(4) The law was further amended in 1984 to include a temporary ''hold harmless'' provision (set forth in paragraph (e) of this section), that was subsequently extended and finally made permanent in 1988.

(5) The law was further amended in 2003 to ensure that amounts payable from the Transitional Assistance Account described in § 403.822 of this chapter shall not be taken into account in computing actuarrial rates or premium amounts.

(b) *Criteria and procedures for the period from July 1976 through December 1983, the period from January 1991 through December 1995, and for periods after December 1998.* (1) For periods from July 1976 through December 1983 and after December 1998, the Secretary determines and promulgates as the standard monthly premium (for disabled as well as aged enrollees) the lower of the following:

(i) The actuarial rate for the aged.

(ii) The monthly premium promulgated the previous December for the year beginning July 1, increased by a percentage that is the same as the latest cost-of-living increase in old age insurance benefits that occurred before the current promulgation. (Because of the change in the effective dates of the premium amount (under paragraph (a)(2) of this section), there was no increase in the standard monthly premium for the period July 1983 through December 1983.)

(2) For periods after December 1998, the Secretary determines the standard monthly premium in the manner specified in paragraph (b)(1) of this section, but promulgates it in September for the following calendar year.

(3) The premiums for calendar years 1991 through 1995 are those amounts as specified by section 1839(e)(1)(B) of the Act as follows:

(i) In 1991, $29.90;

(ii) In 1992, $31.80;

(iii) In 1993, $36.60;

(iv) In 1994, $41.10; and

(v) In 1995, $46.10.

(4) In no case shall payment made for transitional assistance costs under part 403, subpart H of this chapter be included in the formula used to calculate actuarial rates or standard monthly premiums.

(c) *Premiums for calendar years 1984 through 1990 and 1996 through 1998.* For calendar years 1984 through 1990 and 1996 through 1998, the standard monthly premium for all enrollees—

(1) Is equal to 50 percent of the actuarial rate for enrollees age 65 or over, that is, is calculated on the basis of 25 percent of program costs without regard to any cost-of-living increase in old age insurance benefits; and

(2) Is promulgated in the preceding September.

(d) *Limitation on increase of standard premium: 1987 and 1988.* If there is no cost-of-living increase in old age or disability benefits for December 1985 or December 1986, the standard monthly premiums for 1987 and 1988 (promulgated in September 1986 and September 1987, respectively) may not be increased.

(e) *Nonstandard premiums for certain cases*—(1) *Basic rule.* A nonstandard premium may be established in individual cases only if the individual is entitled to old age or disability benefits for the months of November and December, and actually receives the corresponding benefit checks in December and January.

(2) *Special rules: Calendar years 1987 and 1988.* For calendar years 1987 and 1988, the following rules apply:

(i) A nonstandard premium may be established if there is a cost-of-living increase in old age or disability benefits but, because the increase in the standard premium is greater than the cost-of-living increase, the beneficiary would receive a lower cash benefit in January than he or she received in December.

(ii) A nonstandard premium may not be established if the reduction in the individual's benefit would result, in whole or in part, from any circumstance other than the circumstance described in paragraph (e)(2)(i) of this section.

(3) *Special rule: Calendar years after 1988.* (i) Beginning with calendar year 1989, a premium increase greater than the cost-of-living increase is still a prerequisite for a nonstandard premium.

(ii) However, a nonstandard premium is not precluded solely because the cash benefit is further reduced as a result of government pension offset or workers' compensation payment.

(4) *Amount of nonstandard premium.* The nonstandard premium is the greater of the following:

(i) The premium paid for December.

(ii) The standard premium promulgated for January, reduced as necessary to compensate for—

(A) The fact that the cost-of-living increase was less than the increase in the standard premium; or

(B) The further reduction in benefit because of government pension offset or workers' compensation payments.

(5) *Effective dates of nonstandard premium.* A nonstandard premium established under this paragraph (e) continues in effect for the rest of the calendar year even if later there are retroactive adjustments in benefit payments. (The nonstandard premium could be affected by a determination that the individual had not established, or had lost, entitlement to monthly benefits for November or December, or both.)

(6) *Effect of late enrollment or reenrollment.* A nonstandard premium is subject to increase for late enrollment or reenrollment as required under other sections of this subpart. The increase is computed on the basis of the standard premium and added to the nonstandard premium.

[56 FR 8839, Mar. 1, 1991, as amended at 59 FR 26959, May 25, 1994; 68 FR 69927, Dec. 15, 2003]

§ 408.21 Reduction in Medicare Part B premium as an additional benefit under Medicare+Choice plans.

(a) *Basis for reduction in Part B premium.* Beginning January 1, 2003 an M+C organization may elect to receive a reduction in its payments under § 422.250(a)(1) of this chapter if—

(1) 80 percent of the payment reduction is applied to reduce the standard Medicare Part B premiums of its Medicare enrollees.

(2) The Medicare Part B premium is reduced monthly and is offered to all Medicare enrollees in a specific plan benefit package.

(b) *Administrative requirements for the Part B premium reduction.* (1) The Medicare Part B premium reduction cannot be greater than the standard premium amount determined for the year, under section 1839(a)(3) of the Act. However, it may be less.

(2) The Medicare Part B premium reduction must be a multiple of 10 cents.

(3) The Medicare Part B premium reduction is applied regardless of who pays or collects the Part B premium on behalf of the beneficiary.

(4) The Medicare Part B premium can never be less than zero and will never result in a payment to a beneficiary for a specific month.

(c) *Beneficiary eligibility.* In order for a beneficiary to be eligible for the Medicare Part B premium reduction, the beneficiary must be enrolled in an M+C plan that offers the Medicare Part B premium reduction as an additional benefit.

(d) *Notifications.* After determining the Medicare Part B premium reduction amount for each eligible beneficiary, CMS will—

(1) Transmit this information to the Social Security Administration, Railroad Retirement Board, or the Office of Personnel Management, as appropriate, which will adjust the benefit check amounts as appropriate and notify the beneficiaries of their new benefit amount.

(2) Notify states and formal groups and direct billed beneficiaries of their reduced premium amounts in the regular monthly billing process.

[68 FR 66723, Nov. 28, 2003]

§ 408.22 Increased premiums for late enrollment and for reenrollment.

For an individual who enrolls after expiration of his or her initial enrollment period or reenrolls after termination of a coverage period, the standard monthly premium determined under § 408.20 is increased by ten percent for each full twelve months in the periods specified in §§ 408.24 and 408.25.

§ 408.24 Individuals who enrolled or reenrolled before April 1, 1981 or after September 30, 1981.

(a) *Enrollment*. For an individual who first enrolled before April 1, 1981 or after September 30, 1981, the period *includes* the number of months elapsed between the close of the individual's initial enrollment period and the close of the enrollment period in which he or she first enrolled, and *excludes* the following:

(1) The three months of January through March 1968, if the individual first enrolled before April 1968.

(2) Any months before January 1973 during which the individual was precluded from enrolling or reenrolling by the 3-year limitation on enrollment or reenrollment that was in effect before October 30, 1972.

(3) Any months in or before a period of coverage under a State buy-in agreement.

(4) For an individual under age 65, any month before his or her current continuous period of entitlement to hospital insurance.

(5) For an individual age 65 or older, any month before the month he or she attained age 65.

(6) For premiums due for months beginning with September 1984 and ending with May 1986, the following:

(i) Any months after December 1982 during which the individual was—

(A) Age 65 to 69;

(B) Entitled to hospital insurance (Medicare Part A); and

(C) Covered under a group health plan (GHP) by reason of current employment status.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in § 407.20 of this chapter.

(7) For premiums due for months beginning with June 1986, the following:

(i) Any months after December 1982 during which the individual was:

(A) Age 65 or over; and

(B) Covered under a GHP by reason of current employment status.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in § 407.20 of this chapter.

(8) For premiums due for months beginning with January 1987, the following:

(i) Any months after December 1986 and before October 1998 during which the individual was:

(A) A disabled Medicare beneficiary under age 65;

(B) Not eligible for Medicare on the basis of end stage renal disease, under § 406.13 of this chapter; and

(C) Covered under an LGHP as described in § 407.20 of this chapter.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in § 407.20 of this chapter.

(9) For premiums due for months beginning with July 1990, the following:

(i) Any months after December 1986 during which the individual met the conditions of paragraphs (a)(8)(i)(A) and (a)(8)(i)(B) of this section, and was covered under a GHP by reason of the current employment status of the individual or the individual's spouse.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in § 407.20 of this chapter.

(b) *Reenrollment*. For an individual who reenrolled before April 1, 1981 or after September 30, 1981, the period:

(1) *Includes* the following:

(i) The number of months elapsed between the close of the individual's initial enrollment period and the close of the enrollment period in which he or she first enrolled; plus

(ii) The number of months elapsed between the individual's initial period of coverage and the close of the enrollment period in which he or she reenrolled; plus

(iii) The number of months elapsed between each subsequent period of coverage and the close of the enrollment period in which he or she reenrolled.

(2) *Excludes* the following:

(i) The periods specified in paragraphs (a)(1) through (a)(9) of this section; and

(ii) Any month before April 1981 during which the individual was precluded from reenrolling by the two-enrollment limitation in effect before that date.

[52 FR 48118, Dec. 18, 1987, as amended at 53 FR 6648, Mar. 2, 1988; 61 FR 40347, Aug. 2, 1996]

§ 408.25 Individuals who enrolled or reenrolled between April 1 and September 30, 1981.

(a) *Basic rules.* Except as specified in paragraph (b) of this section, the rules set forth in § 408.24 apply to an individual who enrolled or reenrolled between April 1 and September 30, 1981.

(b) *Exception.* For an individual who enrolled or reenrolled between April 1 and September 30, 1981, the months to be counted ran through the month in which he or she reenrolled. (During those 6 months, continuous open enrollment was in effect and there was no 3-month ''general enrollment period''.)

§ 408.26 Examples.

Example 1. Mr. J, who became age 65 and otherwise eligible for enrollment in November 1965, first enrolls in March 1968. The months to be included in determining the amount of the increase in Mr. J's premiums begin with June 1966 (the first month after the close of his initial enrollment period) and extend through December 1967 (the period January through March of 1968 is excluded in determining the total months) for a total of 19 months. Since there is only one full 12-month period in 19 months, Mr. J's premiums will be 10 percent greater than if he had enrolled in his initial enrollment period.

Example 2. Mr. V, who enrolled in December 1965, voluntarily terminates his enrollment effective midnight December 31, 1967. He enrolls for a second time in January 1969. The months to be included in determining the amount of the increase in Mr. V's premiums are January 1968 through March 1969, a total of 15 months. Since this totals one full 12-month period. Mr. V's monthly premium, will be increased by 10 percent.

Example 3. Ms. N becomes age 65 in July 1965 and first enrolls in December 1967. She pays premiums increased by 10 percent above the regular rate, beginning July 1968, the first month of her SMI coverage. Ms. N fails to pay the premiums for the calendar quarter ending June 30, 1970, and her coverage is terminated on that date, the end of her grace period. Ms. N enrolls for a second time in January 1971. The months to be included in determining the amount of the increase in Ms. N's premiums are June 1966 through December 1967, a total of 19 months, and July 1970 through March 1971, a total of 9 months, for a grand total of 28 months. Since this totals two full 12-month periods, Ms. N's monthly premium will be increased by 20 percent.

Example 4. Mr. X attained age 65 in August 1966 and enrolled during his initial enrollment period. His coverage was terminated effective June 30, 1968, for nonpayment of premiums. He reenrolls in March 1973. For purposes of computing any applicable premium increase, he will not be charged any months between March 1971 (the end of the last general enrollment period during which he was eligible to reenroll under the law in effect before October 30, 1972) and January 1973. Therefore, he will be charged 36 months (July 1968–March 1971 plus January 1973–March 1973) and his premiums for his second period of coverage will be increased 30 percent.

Example 5. Ms. C, who attained age 65 in August 1973, had two periods of supplementary medical insurance coverage, both of which were terminated because of nonpayment of premiums: August 1973 through April 1975 and July 1977 through August 1978. She reenrolls in July 1981. The months to be included in determining the amount of premium increase are May 1975 through March 1977 (23 months) and April 1981 through July 1981 (4 months) for a total of 27 months. The 31 months from September 1978 through March 1981 may not be counted because Ms. C was prevented from reenrolling by the two-enrollment limitation in effect before April 1, 1981. For Ms. C, the standard monthly premium would be increased by 20 percent.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

§ 408.27 Rounding the monthly premium.

Any monthly premium that is not a multiple of 10 cents is rounded to the nearest multiple of 10 cents, and any odd mulitple of 5 cents is rounded to the next higher multiple of 10 cents.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

Subpart C—Deduction From Monthly Benefits

§ 408.40 Deduction from monthly benefits: Basic rules.

(a) *Deduction from monthly benefits.* (1) Enrollees who are receiving monthly benefits do not have the option of paying by direct remittance to avoid deduction.

(2) If the enrollee is entitled to more than one type of monthly benefit, the order of priority for deduction is as follows:

(i) Railroad retirement benefits.

(ii) Social security benefits.

(iii) Civil service annuities.

(b) *Deduction from initial or reinstated benefits.* When an enrollee receives a monthly benefit check after an initial award or after a period of suspension, that check is, if administratively feasible, reduced or increased to deduct unpaid premiums or refund premiums paid in advance by direct remittance.

(c) *Ongoing deductions.* The premium for each month is deducted from the cash benefit for the preceding month, e.g., the premium for March is deducted from the benefit for February, which is paid at the beginning of March.

§ 408.42 Deduction from railroad retirement benefits.

(a) *Responsibility for deductions.* If an enrollee is entitled to railroad retirement benefits, his or her SMI premiums are deducted from those benefits by the Railroad Retirement Board (RRB) even though he or she is also entitled to social security benefits or a civil service annuity, or both.

(b) *Action when benefits are suspended.* If the railroad retirement benefits are suspended, the RRB sends premium notices requesting direct remittance, to be made in accordance with the rules set forth in Subpart D of this part.

§ 408.43 Deduction from social security benefits.

SSA, acting as CMS's agent, deducts the premiums from the monthly social security benefits if the enrollee is not entitled to railroad retirement benefits. (If the benefit is less than the monthly premium, the benefit is withheld and the enrollee is required to pay the balance through direct remittance.)

§ 408.44 Deduction from civil service annuities.

(a) *Responsibility for deductions.* If an enrollee is not entitled to railroad retirement benefits or social security benefits, and is receiving a civil service annuity, the premiums are deducted from that annuity by the Office of Personnel Management (OPM) on the basis of a notice from SSA indicating that the annuitant is entitled to SMI.

(b) *Deduction of spouse's premiums.* If the annuitant's spouse is also enrolled for SMI and is not entitled to a civil service annuity or to social security or railroad retirement benefits, and the annuitant gives written consent, OPM also deducts the spouse's premium from the annuitant's monthly check.

(c) *Withdrawal of annuitant's consent.* (1) If an annuitant wishes to withdraw consent for deduction of the spouse's premium, he or she must send written notice of withdrawal to OPM.

(2) The withdrawal notice is effective with the third month after the month in which it is received, or with the month specified in the notice, whichever is later.

§ 408.45 Deduction from age 72 special payments.

(a) *Deduction of premiums.* SMI premiums are deducted from age 72 special payments made under section 228 of the Act or the payments are withheld under procedures that correspond to the rules set forth in §§ 408.40 and 408.43.

(b) *Collection of premiums while age 72 special payments are suspended.* If the age 72 special payments are suspended, CMS or its agent notifies the enrollee to pay premiums by direct remittance, in accordance with the rules set forth in § 408.60.

(c) *Grace period.* The grace period ends with the last day of the third month after the billing month.

(d) *Resumption of age 72 special payments.* (1) If age 72 special payments are resumed before the end of the grace period and all premium arrears can be deducted from those special payments, SMI coverage continues and the enrollee need not pay by direct remittance.

(2) Subsequent special payments are reduced by the amount of the premium for as long as the enrollee receives special payments.

§ 408.46 Effect of suspension of social security benefits.

(a) *Benefit payments to be resumed during the taxable year.* (1) If social security benefit payments are scheduled to be resumed during the enrollee's current taxable year, the enrollee is not billed.

(2) The enrollee may, if he or she wishes, pay the premiums during suspension of benefits.

(b) *Benefit payments not to be resumed during the enrollee's current taxable year.* (1) If social security benefits are suspended for a period that will not permit collection of all premiums due from monthly benefits payable in the enrollee's current taxable year, CMS or its agents bill the enrollee and require direct remittance in accordance with subpart D of this part.

(2) The first billing is for whatever premiums are necessary to place the enrollee in a quarterly cycle.

(3) Thereafter, the billing is on a quarterly basis. (Quarters for different enrollees are staggered throughout the year.)

(4) The enrollee has the option of paying premiums for more than one quarter at the same time.

§ 408.47 [Reserved]

§ 408.50 When premiums are considered paid.

(a) *Actual deduction.* A premium is considered paid if it is actually deducted from a monthly benefit check. Therefore—

(1) The premium is ''paid'' even if SSA later finds that the benefit was paid in error; but

(2) A finding that a monthly benefit was erroneously withheld does not constitute payment of the premium for that month. Since there was no payment, there was no deduction. The enrollee is billed and continuance of coverage depends on payment of premiums before the end of the grace period or extended grace period.

(b) *Payment within the grace period.* Overdue premiums are considered paid within the grace period in the following situations:

(1) *Benefits are resumed during the grace period.* (i) Monthly cash benefit payments are payable for the last month of the initial grace period or for earlier months on the basis of a notice filed by the enrollee before the initial grace period ends; and

(ii) Those payments are sufficient to permit deduction of all overdue premiums.

(2) *Annual earnings report or other report submitted during the grace period shows a benefit is due.* (i) Before the end of the grace period, the enrollee submits a report clearly showing that monthly cash benefits, previously withheld, are payable; and

(ii) Those benefits are sufficient to permit deduction of the full amount of the overdue premiums.

(3) *Premium arrears are paid by direct remittance.* The enrollee makes a direct remittance payment of all overdue premiums before the end of the grace period.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988; 56 FR 48112, Sept. 24, 1991]

§ 408.52 Change from direct remittance to deduction.

If a direct remittance enrollee becomes entitled to monthly benefits—

(a) The SMI premiums are deducted from those benefits; and

(b) The enrollee is notified of the deduction and of any adjustment of the initial benefit check that is required to collect overdue premiums or refund premiums paid in advance.

§ 408.53 Change from partial direct remittance to full deduction.

If a benefit that was less than the premium (and therefore required direct remittance of the difference) is increased to an amount equal to, or greater than, the premium—

(a) The full premium is paid from the benefit; and

(b) Any amounts the enrollee had paid toward premiums not yet due are refunded.

Subpart D—Direct Remittance: Individual Payment

§ 408.60 Direct remittance: Basic rules.

(a) Premiums not deducted from monthly benefits under Subpart C of this part or paid by a State buy-in agreement must be paid by direct remittance to CMS or its agents, by or on behalf of the enrollee.

(b) Quarterly payment is preferred as more cost-effective, but monthly payment is accepted if the enrollee is unwilling or unable to make quarterly payments or is also paying hospital insurance premiums, which must be paid every month.

(c) CMS, directly or through its agents, sends quarterly or monthly premium bills and includes an addressed return envelope with the bill.

(d) The individual must—

(1) Send a check or money order that is drawn payable to ''CMS Medicare Insurance'' and show the enrollee's name and claim number as it appears on the Medicare card; and

(2) Return the bill with the check or money order in the preaddressed envelope.

§ 408.62 Initial and subsequent billings.

(a) *Monthly billing.* (1) The first premium bill is for the period from the first month of coverage (or the first month of change from deduction or State buy-in payment) through the end of the first month after the month of billing.

(2) Subsequent billings are for periods of one month.

(b) *Quarterly billing.* (1) The first premium bill is for the period from the first month of coverage (or of change from deduction or State buy-in payment) through the third month after the month of billing.

(2) Subsequent billings are for periods of three months.

§ 408.63 Billing procedures when monthly benefits are less than monthly premiums.

If monthly benefits are less than monthly premiums, the following procedures apply:

(a) *Notice of amount due.* At the beginning of SMI entitlement, and at the beginning of each succeeding calendar year, SSA—

(1) Notifies the enrollee of the amount of benefits payable for the rest of the year and the total premiums due for those same months; and

(2) Bills the enrollee for the difference.

(b) *Notice of amount overdue.* At the beginning of each succeeding calendar year, SSA—

(1) Notifies the enrollee of any amounts overdue for premiums for the preceding calendar year; and

(2) Indicates that if the amount still overdue on April 30 is equal to or greater than the premium for 3 months, SMI coverage will terminate on that date.

§ 408.65 Payment options.

(a) The enrollee is not asked to pay premiums at the time of enrollment but is instructed to pay them upon receipt of a premium bill from CMS or its agents.

(b) However, if the enrollee wishes, he or she may pay from one to 12 months or from one to four quarters at the time of enrollment.

§ 408.68 When premiums are considered paid.

(a) *Payment by check.* The premium is considered paid if the check is paid by the bank the first or second time it is presented for payment.

(b) *Payment within the grace period.* (1) A premium is considered paid within the grace period if it is delivered personally, or mailed on or before the last day of that period.

(2) A premium payment is considered to have been mailed 7 days before it is received by CMS.

§ 408.70 Change from quarterly to monthly payments.

If an enrollee requests change from quarterly to monthly payment—

(a) If the enrollee is paid up under the quarterly cycle, the first monthly bill is for one month.

(b) If the enrollee is not paid up under the quarter system, the first bill includes all premiums due.

§ 408.71 Change from deduction or State payment to direct remittance.

(a) *Basis for change.* An SMI enrollee is required to pay by direct remittance in any of the following circumstances:

(1) The enrollee's entitlement to social security or railroad retirement benefits ends for any reason other than death.

(2) The premiums can no longer be deducted from the civil service annuity of the enrollee or the enrollee's spouse.

(3) The enrollee no longer qualifies for coverage under a State buy-in agreement, and is not entitled to social security or railroad retirement monthly benefits.

(b) *Billing.* When any of the events specified in paragraph (a) of this section occurs (or as soon thereafter as possible), CMS or its agents bill the enrollee for direct remittance, in accordance with this subpart.

Subpart E—Direct Remittance: Group Payment

§ 408.80 Basic rules.

(a) *Sources of group payment.* An employer, a lodge, union, or other organization may pay SMI premiums on behalf of one or more enrollees.

(b) *Informal arrangement.* Enrollees may turn over their premium notices to their employer, union, lodge, or other organization and that organization may send a single payment (with the premium notices attached so that the payments can readily be identified with the appropriate enrollees) to the CMS Premium Collection Center. Prompt payment is essential since SMI coverage terminates if premiums are not paid by the end of the grace period.

(c) *Group billing arrangement.* CMS may send a single notice for the premiums due from a group of enrollees if the following conditions are met:

(1) The group payer—

(i) Uses funds other than the enrollees' to pay all or a substantial part of the premiums; or

(ii) Deducts the premiums from periodic payments it makes to the enrollees in the group.

(2) The enrollee's rights are protected and enrollees are not required to pay the costs of having their premiums paid on a group basis.

§ 408.82 Conditions for group billing.

CMS agrees to a group billing arrangement only if the following conditions are met:

(a) Conditions the group payer must meet. The group payer submits a written request for group billing—

(1) Showing that all or part of the payments are made from the payer's funds or from funds due the enrollees and in the payer's possession; and

(2) Agreeing not to charge the enrollees for the service of paying the premiums or for the administrative costs such as recordkeeping and postage.

(b) *Enrollees eligible for group payment.* (1) Group payment may be made only on behalf of individuals who are already enrolled and are being billed for direct remittance.

(2) Group payment may not be made for enrollees whose premiums are being deducted from monthly benefits in accordance with Subpart C of this part or being paid by the State under a buy-in agreement.

(c) *Protection of enrollee's rights.* The use of group billing must not jeopardize the enrollees' right—

(1) To confidentiality of personal information;

(2) To terminate enrollment;

(3) To resume individual payment of premiums if he or she wishes; and

(4) To receive notice of any action that affects the SMI benefits.

(d) *Authorization by the enrollee.* (1) To ensure maximum feasible protection of the rights specified in paragraph (c) of this section, each enrollee must give written authorization as specified in § 408.84(a)(2).

(2) A group payer that is not an entity of State or local government must submit all enrollee authorizations to CMS.

(3) A group payer that is an entity of State or local government may retain the authorizations and certify to CMS that it has on file an authorization for each enrollee included in the group.

(4) It is on the basis of the enrollee's authorization that CMS sends the group payer information about each enrollee, as necessary to carry out the group payment function.

(e) *Size of group.* The number of enrollees must be at least 20, which is the minimum size sufficient to make group

billing efficient. (Smaller groups may use the informal procedure described in § 408.80(b).)

§ 408.84 Billing and payment procedures.

(a) *Initial premium notice.* (1) CMS or its agent always sends the initial premium notice to the enrollee.

(2) An enrollee who wishes to have the premiums paid on a group basis must give the notice to the group payer, along with written authorization for sending subsequent notices to the group payer and for release of the information required for the group payment process.

(b) *Monthly billings.* Group premiums are billed on a monthly basis. However, the group payer may pay up to 12 months in advance.

(c) Group payers must make their payments within 30 days after billing, to avoid infringing on the 90-day grace period during which the premiums may be paid by the enrollee if he or she is dropped from the group.

(d) *Effect of group payment.* Payment by a group payer is considered payment by the enrollee.

§ 408.86 Responsibilities under group billing arrangement.

(a) *Enrollee responsibilities.* (1) The enrollee is still responsible for premium payments; the group payer simply acts as his agent. If the agent fails to pay, or identifies the payment incorrectly, SSA notifies both the agent and the enrollee that the enrollee's account is delinquent. If an enrollee fails to take action on that notice, entitlement is terminated for nonpayment of premiums.

(2) The enrollee must promptly notify both SSA and the group payer of any change of address.

(b) *Group payer's responsibilities.* The group payer must—

(1) Make premium payments promptly upon receipt of notices;

(2) Promptly notify both CMS and the enrollee when it drops an enrollee from the group;

(3) Make payments in a way that facilitates efficient and economical processing; and

(4) Maintain the confidentiality of the personal information obtained from CMS for the group payment process.

(c) *CMS responsibilities.* CMS—

(1) Sends the bill to the group payer upon authorization from the enrollee;

(2) Notifies both the payer and the enrollee if the payer fails to make timely payments; and

(3) Refunds excess premiums in accordance with § 408.88.

§ 408.88 Refund of group payments.

(a) *Basis for refund.* Group payments are refunded only in the following circumstances:

(1) The premium was for a month after the month in which the enrollee's SMI coverage terminated or the enrollee died.

(2) The premium was for a month after the month in which the group payer gave notice (before the 26th day of that month) that the enrollee was no longer eligible for group payment and was being dropped from the group.

(b) *Example.* F is the wife of J who is a retiree of Corporation X. That corporation pays premiums on behalf of all of its retirees and their dependents. F obtains a divorce from J on October 20 and thus disqualifies herself for further premium payments by the corporation. The corporation gives notice on November 10 that a refund is due because F has been dropped from the list of persons for whom it has agreed to pay premiums. The premium paid for December would be refunded to the group payer.

(c) *To whom refund is made.* (1) CMS ordinarily refunds to the group payer the premiums specified in paragraph (a) of this section.

(2) However, if CMS has information that clearly shows those premiums were paid from the enrollee's funds, it sends the refund to the enrollee.

§ 408.90 Termination of group billing arrangement.

(a) A group billing arrangement may be terminated either by the group payer or by CMS upon 30 days' notice.

(b) CMS may terminate the arrangement if it finds that the group payer is not acting in the best interest of the enrollees or that, for any other reason, the arrangement has proved inconvenient for CMS.

§ 408.92 Change from group payment to deduction or individual payment.

(a) *Enrollee excluded from group payment arrangement because of entitlement to monthly benefits.* (1) When an enrollee becomes entitled to monthly benefits from which premiums can be deducted as specified in subpart C of this part, CMS notifies the group payer to discontinue payment for that enrollee.

(2) In order to maintain confidentiality, CMS does not explain to the group payer the reason for excluding the enrollee from the group payment arrangement.

(3) The enrollee's premiums are thereafter deducted from the monthly benefits, in accordance with subpart C of this part.

(b) *Enrollee no longer eligible for the group.* (1) When an enrollee is no longer eligible to be included in the group (for instance because he or she is no longer employed by the group payer or has terminated union or lodge membership), the group payer must promptly notify CMS and the enrollee.

(2) CMS or its agents resume sending individual bills to the enrollee, for direct remittance subject to the grace period and termination dates specified in § 408.8.

Subpart F—Termination and Reinstatement of Coverage

§ 408.100 Termination of coverage for nonpayment of premiums.

(a) *Effective date of termination.* Termination is effective on the last day of the grace period. The determination is not made until 15 days after that day to allow for processing of remittances mailed late in the grace period, as provided in § 408.68.

(b) *Notice of termination.* (1) SSA sends the enrollee notice of termination between 15 and 30 days after the end of the grace period and includes information regarding the enrollee's right of appeal.

(2) CMS notifies any intermediary or carrier that had previously been informed that the enrollee had met the SMI deductible for the year in which the termination is effective.

§ 408.102 Reconsideration of termination.

(a) *Basic rules.* Coverage may be reinstated without interruption of benefits if the following conditions are met:

(1) The enrollee appeals the termination by the end of the month following the month in which SSA sent the notice of termination.

(2) The enrollee alleges and it is found that the enrollee did not receive timely and adequate notice that the premiums were overdue.

(3) The enrollee pays, within 30 days after SSA's subsequent request for payment, all premiums due through the month in which he or she appealed the termination.

(b) *Basis for reinstating coverage.* Coverage may be reinstated if the evidence establishes one of the following:

(1) The enrollee acted diligently to pay the premiums or to request relief upon receiving a premium notice very late in the grace period or shortly after its end, and the delayed notice was not the enrollee's fault. (For example, if the billing notice was misaddressed or lost in the mail, it would not be the enrollee's fault; if the enrollee had moved and not notified SSA of the new address, he or she would be responsible for the delay.)

(2) On the basis of information given by SSA, the enrollee could reasonably have believed that the premiums were being paid by deduction from benefits or by some other means. (An example would be a notice indicating that premiums would be paid by a State Medicaid agency or a group payer or would be deducted from the spouse's civil service annuity.)

(c) *No basis for reinstating coverage.* Coverage may not be reinstated if the enrollee—

(1) Received timely and adequate notice but failed to pay within the grace period, for example because of insufficient income or resources; or

(2) Appealed the termination more than one month after the month in which SSA sent the termination notice.

§ 408.104 Reinstatement procedures.

(a) *Request for payment.* If the conditions of § 408.102(a) (1) and (2) are met, SSA sends written notice requesting

the enrollee to pay, within 30 days, all premiums due through the month in which the enrollee appealed the termination.

(b) *Reinstatement of coverage.* If SSA receives the requested payment within 30 days, it sets aside the termination and reinstates the enrollee's coverage without interruption.

Subpart G—Collection of Unpaid Premiums; Refund of Excess Premiums After the Death of the Enrollee

§ 408.110 Collection of unpaid premiums.

(a) *Basis and scope*—(1) *Basis.* Under the Federal Claims Collection Act of 1966 (31 U.S.C. 3711), CMS is required to collect any debts due it but is authorized to suspend or terminate collection action on debts of less than $20,000 when certain conditions are met. (See 4 CFR, parts 101–105 for general rules implementing the Federal Claims Collection Act.) As indicated in § 408.4, unpaid premiums are debts owed the Federal government by the enrollee or the enrollee's estate.

(2) *Scope.* This section sets forth the methods of collection used by CMS and the circumstances under which CMS terminates or renews collection action. The regulations in this section apply to hospital insurance premiums as well as SMI premiums.

(b) *Collection of unpaid premiums.* Generally, CMS will attempt to collect unpaid premiums by one of the following methods:

(1) By billing enrollees who pay the premiums directly to CMS or to a designated agent in accordance with § 408.60.

(2) By deduction from any benefits payable to the enrollee or the estate of a deceased enrollee under Title II or XVIII of the Social Security Act, the Railroad Retirement Act or any act administered by the Office of Personnel Management in accordance with § 408.4(b) and Subpart C of this part (Deduction from Monthly Benefits); or

(3) By billing the estate of a deceased enrollee.

(c) *Termination of collection action.* CMS terminates collection action on unpaid premiums under either of the following circumstances, if the cost of collection exceeds the amount of overdue premiums:

(1) The individual is not entitled to benefits under the Acts listed in paragraph (b)(2) of this section, is not currently enrolled for SMI or premium hospital insurance, and demonstrates, to CMS's satisfaction, that he or she is unable to pay the debt within a reasonable time.

(2) The individual has been dead more than 27 months (the maximum time allowed for claiming SMI benefits), and the legal representative of his or her estate demonstrates, to CMS's satisfaction, that the estate is unable to pay the debt within a reasonable time.

(d) *Renewal of collection efforts.* CMS renews collection efforts in either of the following circumstances, if the cost of collection does not exceed the amount of the overdue premiums:

(1) The individual enrolls again for premium hospital insurance or SMI. (Payment of overdue premiums is not a prerequisite for reenrollment.)

(2) The individual becomes entitled or reentitled to social security or railroad retirement benefits or a Federal civil service annuity.

§ 408.112 Refund of excess premiums after the enrollee dies.

If CMS has received premiums for months after the enrollee's death, CMS refunds those premiums as follows:

(a) To the person or persons who paid the premiums or, if the premiums were paid by the enrollee, to the representative of the enrollee's estate, if any.

(b) If refund cannot be made under paragraph (a) of this section, CMS refunds the premiums to the enrollee's survivors in the following order of priority:

(1) The surviving spouse, if he or she was either living in the same household with the deceased at the time of death, or was, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(2) The child or children who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased

(and, if there is more than one child, in equal parts to each child);

(3) The parent or parents who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent);

(4) The surviving spouse who was not living in the same household with the deceased at the time of death and was not, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(5) The child or children who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(6) The parent or parents who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent).

If none of the listed relatives survives, no refund can be made.

Subpart H—Supplementary Medical Insurance Premium Surcharge Agreements

SOURCE: 67 FR 60996, Sept. 27, 2002, unless otherwise noted.

§ 408.200 Statutory basis.

This subpart implements provisions of section 1839(e) of the Social Security Act that allow State or local government agencies to enter into an agreement with the Secretary to pay, on a quarterly or other periodic basis, a lump sum for the total of the SMI premium late enrollment surcharge amounts due for a group of eligible enrollees.

§ 408.201 Definitions.

For purposes of this subpart, the following definitions apply:

SMI premium surcharge means the amount that the standard monthly SMI premium is increased for late enrollment or for reenrollment as specified in §§ 408.22 through 408.25.

SMI premium surcharge agreement means a written arrangement between the Secretary and a State or local government agency to pay, on a quarterly, monthly, or other periodic basis, a lump sum for the SMI premium surcharge amounts due for a designated group of eligible enrollees.

§ 408.202 Conditions for participation.

(a) A State or local government agency may apply to CMS to enter into an SMI premium surcharge agreement if the following conditions are met:

(1) Each individual designated for coverage under the premium surcharge agreement must be enrolled in Medicare Part B at the time the individual is added to the premium surcharge account.

(2) Each enrollee designated for coverage under the agreement must, at the time the individual is added to the premium surcharge account, be responsible for paying the base premium and surcharge through direct remittance or benefit withholding from Social Security or Railroad Retirement benefits or a Civil Service annuity.

(3) Each enrollee designated for coverage under the agreement must, at the time the individual is added to the premium surcharge account, not have premiums paid by a State Welfare Agency under a State buy-in agreement as described in § 407.40 of this chapter or under a group billing arrangement as described in § 408.80.

(b) The State or local government agency must secure from each enrollee a signed, written statement authorizing CMS to send billing notices directly to the State or local government agency, and to release to the State or local government agency information required under the SMI premium surcharge agreement.

(c) The authorization statement for each enrollee must be retained in the State or local government agency files for as long as the enrollee is covered by the agreement. These authorization statements need not be forwarded to CMS.

(d) The State or local government agency must certify to CMS, in writing, that an authorization statement is

on file for each enrollee covered under the SMI premium surcharge agreement. Only one certification is necessary for the entire group of covered enrollees.

(e) A State or local government agency must establish an automated data exchange with CMS using the Third Party Premium Collection System, in order to transmit electronically an input file that will be used to add or remove enrollees from the billing system.

§ 408.205 Application procedures.

(a) A State or local government agency must contact its CMS regional office (RO) to request application materials.

(b) If interested in entering into an agreement, the State or local government agency must return to the RO two copies of the completed application materials.

(c) CMS reviews the application materials, and, when they are approved, notifies the State or local government agency, and the RO.

§ 408.207 Billing and payment procedures.

(a) *Adding and removing enrollees.* The State or local government agency must transmit an input file containing addition and removal records electronically to CMS as follows:

(1) Input files must be transmitted at least once each calendar month, but may be transmitted as often as once a day.

(2) CMS will not add or remove enrollees retroactively, except for removals upon the death of an enrollee.

(3) The State or local government agency must pay the SMI premium surcharge for each eligible enrollee who is included in the agreement for the time period beginning with the month the enrollee is added and continuing through the month the State or local government agency informs CMS that the enrollee is to be removed, the month the enrollee's Part B coverage terminates, or the month of the enrollee's death, whichever comes first.

(b) *Payment and grace period.* Payment must be made to CMS as follows:

(1) Payment to CMS must be received by CMS by the first day of each month.

(2) There is a 10-day grace period for receipt of payment.

(3) Payment must be made to CMS via electronic funds transfer.

(c) *Late payment penalties.* CMS may assess interest for any payment it does not receive by the first day of the month as follows:

(1) Interest will be assessed at the SMI trust fund rate as computed for new investments in accordance with section 1841(c) of the Act.

(2) Interest will be waived if the full payment is received by the 10th day of the month in which it is due.

(3) Interest will be calculated and assessed in 30-day increments.

(4) Interest will be assessed on the balance of the amount billed that remains unpaid at the expiration of the grace period and unpaid balances from prior periods.

(5) Interest will continue to accrue on unpaid amounts until the balance is paid in full.

(d) *Disagreement over billing amounts or interest.* If the State or local government agency disagrees with the amount assessed in a billing statement or interest charge, it must notify CMS as follows:

(1) The State or local government agency must provide evidence suitable to CMS to substantiate its claim.

(2) The State or local government agency must continue to make full payment while CMS evaluates the evidence provided.

(3) Credit for payment amounts or interest that CMS determines to be due to the State or local government agency will be reflected as an adjustment in subsequent bills, effective on the date the corrected amount would have been due.

§ 408.210 Termination of SMI premium surcharge agreement.

(a) *Termination by the State or local government agency.* The State or local government agency may voluntarily terminate its agreement with CMS as follows:

(1) The State or local government agency must notify CMS, in writing, at least 30 days before the effective date of the termination.

(2) The State or local government agency must pay any unpaid premium

surcharge amounts and interest due within 30 days after the effective date of the termination.

(3) Interest will continue to accrue until all amounts due are paid in full.

(b) *Termination by CMS.* CMS may terminate the agreement with a State or local government agency as follows:

(1) If a State or local government agency's payments are delinquent 30 days or more, CMS may terminate the agreement with 30 days advance notice.

(2) If the State or local government agency fails to comply with the terms of the agreement or procedures promulgated by CMS, CMS may terminate the agreement with 30 days advance notice.

(3) If CMS finds that the State or local government agency is not acting in the best interest of the enrollees, or CMS, or for any reason other than those in paragraphs (b)(1) and (b)(2) of this section, CMS may terminate the agreement at any time.

(4) The State or local government agency must pay all outstanding premium surcharge and any interest amounts due within 30 days after the effective date of the termination.

(5) Interest will continue to accrue until all amounts due are paid in full.

(6) After the agreement is terminated, CMS will resume collection of the premium surcharge from the enrollees covered under the terminated agreement.

(7) If an agreement is terminated by CMS, the State or local government agency must wait 3 years from the effective date of the termination before it can request to enter into another SMI premium surcharge agreement.

PART 409—HOSPITAL INSURANCE BENEFITS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 48 FR 12541, Mar. 25, 1983, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 409 appear at 62 FR 46037, Aug. 29, 1997.

Subpart A—Hospital Insurance Benefits: General Provisions

§ 409.1 Statutory basis.

This part is based on the identified provisions of the following sections of the Social Security Act:

(a) Sections 1812 and 1813 establish the scope of benefits of the hospital insurance program under Medicare Part A and set forth deductible and coinsurance requirements.

(b) Sections 1814 and 1815 establish conditions for, and limitations on, payment for services furnished by providers.

(c) Section 1820 establishes the critical access hospital program.

(d) Section 1861 describes the services covered under Medicare Part A, and benefit periods.

(e) Section 1862(a) specifies exclusions from coverage.

(f) Section 1881 sets forth the rules for individuals who have end-stage renal disease (ESRD), for organ donors, and for dialysis, transplantation, and other services furnished to ESRD patients.

[60 FR 50441, Sept. 29, 1995, as amended at 65 FR 62646, Oct. 19, 2000]

§ 409.2 Scope.

Subparts A through G of this part describe the benefits available under Medicare Part A and set forth the limitations on those benefits, including certain amounts of payment for which beneficiaries are responsible.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 409.3 Definitions.

As used in this part, unless the context indicates otherwise—

Arrangements means arrangements which provide that Medicare payment made to the provider that arranged for the services discharges the liability of the beneficiary or any other person to pay for those services.

Covered refers to services for which the law and the regulations authorize Medicare payment.

Nominal charge provider means a provider that furnishes services free of charge or at a nominal charge and is either a public provider, or another provider that (1) demonstrates to CMS's satisfaction that a significant portion of its patients are low-income, and (2) requests that payment for its services be determined accordingly.

Participating refers to a hospital or other facility that meets the conditions of participation and has in effect a Medicare provider agreement.

Qualified hospital means a facility that—

(a) Is primarily engaged in providing, by or under the supervision of doctors of medicine or osteopathy, inpatient services for the diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled;

(b) Is not primarily engaged in providing skilled nursing care and related services for inpatients who require medical or nursing care;

(c) Provides 24-hour nursing service in accordance with Sec. 1861(e)(5) of the Act;

(d) If it is a U.S. hospital, is licensed, or approved as meeting the standards for licensing, by the State or local licensing agency; and

(e) If it is a foreign hospital, is licensed, or approved as meeting the standard for licensing, by the appropriate Canadian or Mexican licensing agency, and for purposes of furnishing non-emergency services to U.S. residents, is accredited by the Joint Commission on Accreditation of Hospitals (JCAH), or by a Canadian or Mexican program under standards that CMS finds to be equivalent to those of the JCAH.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986]

§ 409.5 General description of benefits.

Hospital insurance (Part A of Medicare) helps pay for inpatient hospital or inpatient CAH services and posthospital SNF care. It also pays for home health services and hospice care. There are limitations on the number of days of care that Medicare can pay for and there are deductible and coinsurance amounts for which the beneficiary is responsible. For each type of service, certain conditions must be met as specified in the pertinent sections of this subpart and in part 418 of this chapter regarding hospice care. The special conditions for inpatient hospital services furnished by a qualified U.S., Canadian, or Mexican hospital are set forth in subparts G and H of part 424 of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 53 FR 6648, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 58 FR 30666, May 26, 1993]

Subpart B—Inpatient Hospital Services and Inpatient Critical Access Hospital Services

§ 409.10 Included services.

(a) Subject to the conditions, limitations, and exceptions set forth in this subpart, the term ''inpatient hospital or inpatient CAH services'' means the following services furnished to an inpatient of a participating hospital or of a participating CAH or, in the case of emergency services or services in foreign hospitals, to an inpatient of a qualified hospital:

(1) Bed and board.

(2) Nursing services and other related services.

(3) Use of hospital or CAH facilities.

(4) Medical social services.

(5) Drugs, biologicals, supplies, appliances, and equipment.

(6) Certain other diagnostic or therapeutic services.

(7) Medical or surgical services provided by certain interns or residents-in-training.

(8) Transportation services, including transport by ambulance.

(b) *Inpatient hospital services* does not include the following types of services:

(1) Posthospital SNF care, as described in § 409.20, furnished by a hospital or a critical access hospital that has a swing-bed approval.

(2) Nursing facility services, described in § 440.155 of this chapter, that may be furnished as a Medicaid service under title XIX of the Act in a swing-bed hospital that has an approval to furnish nursing facility services.

(3) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(4) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(5) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(6) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(7) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(8) Services of an anesthetist, as defined in § 410.69

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, May 26, 1993; 64 FR 3648, Jan. 25, 1999; 65 FR 18535, Apr. 7, 2000]

§ 409.11 Bed and board.

(a) *Semiprivate and ward accommodations.* Except for applicable deductible and coinsurance amounts, Medicare Part A pays in full for bed and board and semiprivate (2 to 4 beds), or ward (5 or more beds) accommodations.

(b) *Private accommodations*—(1) *Conditions for payment in full.* Except for applicable deductible and coinsurance amounts, Medicare Part A pays in full for a private room if—

(i) The patient's condition requires him or her to be isolated;

(ii) The hospital or CAH has no semiprivate or ward accommodations; or

(iii) The hospital's or CAH's semiprivate and ward accommodations are fully occupied by other patients, were so occupied at the time the patient was admitted to the hospital or CAH, respectively, for treatment of a condition that required immediate inpatient hospital or inpatient CAH care, and have been so occupied during the interval.

(2) *Period of payment.* In the situations specified in paragraph (b)(1) (i) and (iii) of this section, Medicare pays for a private room until the patient's condition no longer requires isolation or until semiprivate or ward accommodations are available.

(3) *Conditions for patient's liability.* The hospital or CAH may charge the patient the difference between its customary charge for the private room and its most prevalent charge for a semiprivate room if—

(i) None of the conditions of paragraph (b)(1) of this section is met; and

(ii) The private room was requested by the patient or a member of the family, who, at the time of the request, was informed what the hospital's or CAH's charge would be.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.12 Nursing and related services, medical social services; use of hospital or CAH facilities.

(a) Except as provided in paragraph (b) of this section, Medicare pays for nursing and related services, use of hospital or CAH facilities, and medical social services as inpatient hospital or inpatient CAH services only if those services are ordinarily furnished by the hospital or CAH, respectively, for the care and treatment of inpatients.

(b) *Exception.* Medicare does not pay for the services of a private duty nurse or attendant. An individual is not considered to be a private duty nurse or attendant if he or she is a hospital or CAH employee at the time the services are furnished.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, 30667, May 26, 1993]

§ 409.13 Drugs and biologicals.

(a) Except as specified in paragraph (b) of this section, Medicare pays for drugs and biologicals as inpatient hospital or inpatient CAH services only if—

(1) They represent a cost to the hospital or CAH;

(2) They are ordinarily furnished by the hospital or CAH for the care and treatment of inpatients; and

(3) They are furnished to an inpatient for use in the hospital or CAH.

(b) *Exception.* Medicare pays for a limited supply of drugs for use outside the hospital or CAH if it is medically necessary to facilitate the beneficiary's departure from the hospital and required until he or she can obtain a continuing supply.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.14 Supplies, appliances, and equipment.

(a) Except as specified in paragraph (b) of this section, Medicare pays for supplies, appliances, and equipment as inpatient hospital or inpatient CAH services only if—

(1) They are ordinarily furnished by the hospital or CAH to inpatients; and

(2) They are furnished to inpatients for use in the hospital or CAH.

(b) *Exceptions.* Medicare pays for items to be used beyond the hospital or CAH stay if—

(1) The item is one that the beneficiary must continue to use after he or she leaves the hospital or CAH, for example, heart valves or a heart pacemaker, or

(2) The item is medically necessary to permit or facilitate the beneficiary's departure from the hospital or CAH and is required until the beneficiary can obtain a continuing supply. Tracheostomy or draining tubes are examples.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.15 Services furnished by an intern or a resident-in-training.

Medical or surgical services provided by an intern or a resident-in-training are included as ''inpatient hospital or inpatient CAH services'' if they are provided—

(a) By an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association, or the Bureau of Professional Education of the American Osteopathic Association;

(b) By an intern or a resident-in-training in the field of dentistry under a teaching program approved by the Council on Dental Education of the American Dental Association; or

(c) By an intern or a resident-in-training in the field of podiatry under a teaching program approved by the Council on Podiatry Education of the American Podiatry Association.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.16 Other diagnostic or therapeutic services.

Diagnostic or therapeutic services other than those provided for in §§ 409.12, 409.13, and 409.14 are considered as inpatient hospital or inpatient CAH services if—

(a) They are furnished by the hospital or CAH, or by others under arrangements made by the hospital or CAH;

(b) Billing for those services is through the hospital or CAH; and

(c) The services are of a kind ordinarily furnished to inpatients either by the hospital or CAH or under arrangements made by the hospital or CAH.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.18 Services related to kidney transplantations.

(a) *Kidney transplants*. Medicare pays for kidney transplantation surgery only if performed in a renal transplantation center approved under subpart U of part 405 of this chapter.

(b) *Services in connection with kidney donations*. Medicare pays for services related to the evaluation or preparation of a potential or actual donor, to the donation of the kidney, or to postoperative recovery services directly related to the kidney donation—

(1) If the kidney is intended for an individual who has ESRD and is entitled to Medicare benefits or can be expected to become so entitled within a reasonable time; and

(2) Regardless of whether the donor is entitled to Medicare.

Subpart C—Posthospital SNF Care

§ 409.20 Coverage of services.

(a) *Included services*. Subject to the conditions and limitations set forth in this subpart and subpart D of this part, ''posthospital SNF care'' means the following services furnished to an inpatient of a participating SNF, or of a participating hospital or critical access hospital (CAH) that has a swing-bed approval:

(1) Nursing care provided by or under the supervision of a registered professional nurse.

(2) Bed and board in connection with the furnishing of that nursing care.

(3) Physical, occupational, or speech therapy.

(4) Medical social services.

(5) Drugs, biologicals, supplies, appliances, and equipment.

(6) Services furnished by a hospital with which the SNF has a transfer agreement in effect under § 483.75(n) of this chapter.

(7) Other services that are generally provided by (or under arrangements made by) SNFs.

(b) *Excluded services*—(1) *Services that are not considered inpatient hospital services*. No service is included as posthospital SNF care if it would not be included as an inpatient hospital service under §§ 409.11 through 409.18.

(2) *Services not generally provided by (or under arrangements made by) SNFs*. Except as specifically listed in §§ 409.21 through 409.27, only those services generally provided by (or under arrangements made by) SNFs are considered as posthospital SNF care. For example, a type of medical or surgical procedure that is ordinarily performed only on an

inpatient basis in a hospital is not included as ''posthospital SNF care,'' because such procedures are not generally provided by (or under arrangements made by) SNFs.

(c) *Terminology*. In § 409.21 through § 409.36—.

(1) The terms *SNF* and *swing-bed hospital* are used when the context applies to the particular facility.

(2) The term *facility* is used to mean both SNFs and swing-bed hospitals.

(3) The term *swing-bed hospital* includes a CAH with swing-bed approval under subpart F of part 485 of this chapter.

(4) The term *post-hospital SNF care* includes SNF care that does not follow a hospital stay when the beneficiary is enrolled in a plan, as defined in § 422.4 of this chapter, offered by a Medicare+Choice (M+C) organization, that includes the benefits described in § 422.101(c) of this chapter.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30667, May 26, 1993; 63 FR 26306, May 12, 1998; 64 FR 3648, Jan. 25, 1999; 64 FR 41681, July 30, 1999; 68 FR 46070, Aug. 4, 2003; 68 FR 50854, Aug. 22, 2003; 69 FR 35529, June 25, 2004]

§ 409.21 Nursing care.

(a) *Basic rule*. Medicare pays for nursing care as posthospital SNF care when provided by or under the supervision of a registered professional nurse.

(b) *Exception*. Medicare does not pay for the services of a private duty nurse or attendant. An individual is not considered to be a private duty nurse or attendant if he or she is an SNF employee at the time the services are furnished.

[63 FR 26306, May 12, 1998]

§ 409.22 Bed and board.

(a) *Semiprivate and ward accommodations*. Except for applicable deductible and coinsurance amounts Medicare Part A pays in full for semiprivate (2 to 4 beds), or ward (5 or more beds) accommodations.

(b) *Private accommodations*—(1) *Conditions for payment in full*. Except for applicable coinsurance amounts, Medicare pays in full for a private room if—

(i) The patient's condition requires him to be isolated;

(ii) The SNF has no semiprivate or ward accommodations; or

(iii) The SNF semiprivate and ward accommodations are fully occupied by other patients, were so occupied at the time the patient was admitted to the SNF for treatment of a condition that required immediate inpatient SNF care, and have been so occupied during the interval.

(2) *Period of payment*. In the situations specified in paragraph (b)(1) (i) and (iii) of this section. Medicare pays for a private room until the patient's condition no longer requires isolation or until semiprivate or ward accommodations are available.

(3) *Conditions for patient's liability*. The facility may charge the patient the difference between its customary charge for the private room furnished and its most prevalent charge for a semiprivate room if:

(i) None of the conditions of paragraph (b)(1) of this section is met, and

(ii) The private room was requested by the patient or a member of the family who, at the time of request was informed what the charge would be.

§ 409.23 Physical, occupational, and speech therapy.

Medicare pays for physical, occupational, or speech therapy as posthospital SNF care if—

(a) It is furnished by the facility or under arrangements made by the facility, and

(b) Billing for the therapy is by or through the facility.

§ 409.24 Medical social services.

Medicare pays for medical social services as posthospital SNF care, including—

(a) Assessment of the social and emotional factors related to the beneficiary's illness, need for care, response to treatment, and adjustment to care in the facility;

(b) Case work services to assist in resolving social or emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment; and

(c) Assessment of the relationship of the beneficiary's medical and nursing

requirements to his or her home situation, financial resources, and the community resources available upon discharge from facility care.

[63 FR 26306, May 12, 1998]

§ 409.25 Drugs, biologicals, supplies, appliances, and equipment.

(a) *Drugs and biologicals*. Except as specified in paragraph (b) of this section, Medicare pays for drugs and biologicals as posthospital SNF care only if—

(1) They represent a cost to the facility;

(2) They are ordinarily furnished by the facility for the care and treatment of inpatients; and

(3) They are furnished to an inpatient for use in the facility.

(b) *Exception*. Medicare pays for a limited supply of drugs for use outside the facility if it is medically necessary to facilitate the beneficiary's departure from the facility and required until he or she can obtain a continuing supply.

(c) *Supplies, appliances, and equipment*. Except as specified in paragraph (d) of this section, Medicare pays for supplies, appliances, and equipment as posthospital SNF care only if they are—

(1) Ordinarily furnished by the facility to inpatients; and

(2) Furnished to inpatients for use in the facility.

(d) *Exception*. Medicare pays for items to be used after the individual leaves the facility if—

(1) The item is one that the beneficiary must continue to use after leaving, such as a leg brace; or

(2) The item is necessary to permit or facilitate the beneficiary's departure from the facility and is required until he or she can obtain a continuing supply, for example, sterile dressings.

[63 FR 26307, May 12, 1998]

§ 409.26 Transfer agreement hospital services.

(a) *Services furnished by an intern or a resident-in-training*. Medicare pays for medical services that are furnished by an intern or a resident-in-training (under a hospital teaching program approved in accordance with the provisions of § 409.15) as posthospital SNF care, if the intern or resident is in—

(1) A participating hospital with which the SNF has in effect an agreement under § 483.75(n) of this chapter for the transfer of patients and exchange of medical records; or

(2) A hospital that has a swing-bed approval, and is furnishing services to an SNF-level inpatient of that hospital.

(b) *Other diagnostic or therapeutic services*. Medicare pays for other diagnostic or therapeutic services as posthospital SNF care if they are provided—

(1) By a participating hospital with which the SNF has in effect a transfer agreement as described in paragraph (a)(1) of this section; or

(2) By a hospital or a CAH that has a swing-bed approval, to its own SNF-level inpatient.

[63 FR 26307, May 12, 1998]

§ 409.27 Other services generally provided by (or under arrangements made by) SNFs.

In addition to those services specified in §§ 409.21 through 409.26, Medicare pays as posthospital SNF care for such other diagnostic and therapeutic services as are generally provided by (or under arrangements made by) SNFs, including—

(a) Medical and other health services as described in subpart B of part 410 of this chapter, subject to any applicable limitations or exclusions contained in that subpart or in § 409.20(b);

(b) Respiratory therapy services prescribed by a physician for the assessment, diagnostic evaluation, treatment, management, and monitoring of patients with deficiencies and abnormalities of cardiopulmonary function; and

(c) Transportation by ambulance that meets the general medical necessity requirements set forth in § 410.40(d)(1) of this chapter.

[63 FR 26307, May 12, 1998, as amended at 64 FR 41681, July 30, 1999]

Subpart D—Requirements for Coverage of Posthospital SNF Care

§ 409.30 Basic requirements.

Posthospital SNF care, including SNF-type care furnished in a hospital or CAH that has a swing-bed approval, is covered only if the beneficiary meets the requirements of this section and only for days when he or she needs and receives care of the level described in § 409.31. A beneficiary in an SNF is also considered to meet the level of care requirements of § 409.31 up to and including the assessment reference date for the 5-day assessment prescribed in § 413.343(b) of this chapter, when assigned to one of the Resource Utilization Groups that is designated (in the annual publication of Federal prospective payment rates described in § 413.345 of this chapter) as representing the required level of care. For the purposes of this section, the assessment reference date is defined in accordance with § 483.315(d) of this chapter, and must occur no later than the eighth day of posthospital SNF care.

(a) *Pre-admission requirements.* The beneficiary must—

(1) Have been hospitalized in a participating or qualified hospital or participating CAH, for medically necessary inpatient hospital or inpatient CAH care, for at least 3 consecutive calendar days, not counting the date of discharge; and

(2) Have been discharged from the hospital or CAH in or after the month he or she attained age 65, or in a month for which he or she was entitled to hospital or CAH insurance benefits on the basis of disability or end-stage renal disease, in accordance with part 406 of this chapter.

(b) *Date of admission requirements.*[1] (1) Except as specified in paragraph (b)(2) of this section, the beneficiary must be in need of posthospital SNF care, be admitted to the facility, and receive the needed care within 30 calendar days after the date of discharge from a hospital or CAH.

(2) The following exceptions apply—

(i) A beneficiary for whom posthospital SNF care would not be medically appropriate within 30 days after discharge from the hospital or CAH, or a beneficiary enrolled in a Medicare+Choice (M+C) plan, may be admitted at the time it would be medically appropriate to begin an active course of treatment.

(ii) If, upon admission to the SNF, the beneficiary was enrolled in an M+C plan, as defined in § 422.4 of this chapter, offering the benefits described in § 422.101(c) of this chapter, the beneficiary will be considered to have met the requirements described in paragraphs (a) and (b) of this section, and also in § 409.31(b)(2), for the duration of the SNF stay.

[48 FR 12541, Mar. 25, 1983, as amended at 51 FR 41338, Nov. 14, 1986; 58 FR 30666, 30667, May 26, 1993; 62 FR 46025, Aug. 29, 1997; 63 FR 26307, May 12, 1998; 64 FR 41681, July 30, 1999; 68 FR 50584, Aug. 22, 2003]

§ 409.31 Level of care requirement.

(a) *Definition.* As used in this section, *skilled nursing and skilled rehabilitation services* means services that:

(1) Are ordered by a physician;

(2) Require the skills of technical or professional personnel such as registered nurses, licensed practical (vocational) nurses, physical therapists, occupational therapists, and speech pathologists or audiologists; and

(3) Are furnished directly by, or under the supervision of, such personnel.

(b) *Specific conditions for meeting level of care requirements.* (1) The beneficiary must require skilled nursing or skilled rehabilitation services, or both, on a daily basis.

(2) Those services must be furnished for a condition—

(i) For which the beneficiary received inpatient hospital or inpatient CAH services; or

(ii) Which arose while the beneficiary was receiving care in a SNF or swing-bed hospital for a condition for which

[1] Before December 5, 1980, the law required that admission and receipt of care be within 14 days after discharge from the hospital or CAH and permitted admission up to 28 days after discharge if a SNF bed was not available in the geographic area in which the patient lived, or at the time it would be medically appropriate to begin an active course of treatment, if SNF care would not be medically appropriate within 14 days after discharge.

he or she received inpatient hospital or inpatient CAH services; or

(iii) For which, for an M+C enrollee described in § 409.20(c)(4), a physician has determined that a direct admission to a SNF without an inpatient hospital or inpatient CAH stay would be medically appropriate.

(3) The daily skilled services must be ones that, as a practical matter, can only be provided in a SNF, on an inpatient basis.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993; 68 FR 50854, Aug. 22, 2003; 70 FR 45055, Aug. 4, 2005]

§ 409.32 Criteria for skilled services and the need for skilled services.

(a) To be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel.

(b) A condition that does not ordinarily require skilled services may require them because of special medical complications. Under those circumstances, a service that is usually nonskilled (such as those listed in § 409.33(d)) may be considered skilled because it must be performed or supervised by skilled nursing or rehabilitation personnel. For example, a plaster cast on a leg does not usually require skilled care. However, if the patient has a preexisting acute skin condition or needs traction, skilled personnel may be needed to adjust traction or watch for complications. In situations of this type, the complications, and the skilled services they require, must be documented by physicians' orders and nursing or therapy notes.

(c) The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities. For example, a terminal cancer patient may need some of the skilled services described in § 409.33.

[48 FR 12541, Mar. 25, 1983, as amended at 59 FR 65493, Dec. 20, 1994]

§ 409.33 Examples of skilled nursing and rehabilitation services.

(a) *Services that could qualify as either skilled nursing or skilled rehabilitation services*—(1) *Overall management and evaluation of care plan.* (i) When overall management and evaluation of care plan *constitute skilled services.* The development, management, and evaluation of a patient care plan based on the physician's orders constitute skilled services when, because of the patient's physical or mental condition, those activities require the involvement of technical or professional personnel in order to meet the patient's needs, promote recovery, and ensure medical safety. Those activities include the management of a plan involving a variety of personal care services only when, in light of the patient's condition, the aggregate of those services requires the involvement of technical or professional personnel.

(ii) *Example.* An aged patient with a history of diabetes mellitus and angina pectoris who is recovering from an open reduction of a fracture of the neck of the femur requires, among other services, careful skin care, appropriate oral medications, a diabetic diet, an exercise program to preserve muscle tone and body condition, and observation to detect signs of deterioration in his or her condition or complications resulting from restricted, but increasing, mobility. Although any of the required services could be performed by a properly instructed person, such a person would not have the ability to understand the relationship between the services and evaluate the ultimate effect of one service on the other. Since the nature of the patient's condition, age, and immobility create a high potential for serious complications, such an understanding is essential to ensure the patient's recovery and safety. Under these circumstances, the management of the plan of care would require the skills of a nurse even though the individual services are not skilled. Skilled planning and management activities are not always specifically identified in the patient's clinical record. Therefore, if the patient's overall condition supports a finding that recovery and safety can be ensured

only if the total care is planned, managed, and evaluated by technical or professional personnel, it is appropriate to infer that skilled services are being provided.

(2) *Observation and assessment of the patient's changing condition*—(i) *When observation and assessment constitute skilled services.* Observation and assessment constitute skilled services when the skills of a technical or professional person are required to identify and evaluate the patient's need for modification of treatment or for additional medical procedures until his or her condition is stabilized.

(ii) *Examples.* A patient with congestive heart failure may require continuous close observation to detect signs of decompensation, abnormal fluid balance, or adverse effects resulting from prescribed medication(s) that serve as indicators for adjusting therapeutic measures. Similarly, surgical patients transferred from a hospital to an SNF while in the complicated, unstabilized postoperative period, for example, after hip prosthesis or cataract surgery, may need continued close skilled monitoring for postoperative complications and adverse reaction. Patients who, in addition to their physical problems, exhibit acute psychological symptoms such as depression, anxiety, or agitation, may also require skilled observation and assessment by technical or professional personnel to ensure their safety or the safety of others, that is, to observe for indications of suicidal or hostile behavior. The need for services of this type must be documented by physicians' orders or nursing or therapy notes.

(3) *Patient education services*—(i) *When patient education services constitute skilled services.* Patient education services are skilled services if the use of technical or professional personnel is necessary to teach a patient self-maintenance.

(ii) *Examples.* A patient who has had a recent leg amputation needs skilled rehabilitation services provided by technical or professional personnel to provide gait training and to teach prosthesis care. Similarly, a patient newly diagnosed with diabetes requires instruction from technical or professional personnel to learn the self-administration of insulin or foot-care precautions.

(b) *Services that qualify as skilled nursing services.* (1) Intravenous or intramuscular injections and intravenous feeding.

(2) Enteral feeding that comprises at least 26 per cent of daily calorie requirements and provides at least 501 milliliters of fluid per day.

(3) Nasopharyngeal and tracheostomy aspiration;

(4) Insertion and sterile irrigation and replacement of suprapubic catheters;

(5) Application of dressings involving prescription medications and aseptic techniques;

(6) Treatment of extensive decubitus ulcers or other widespread skin disorder;

(7) Heat treatments which have been specifically ordered by a physician as part of active treatment and which require observation by nurses to adequately evaluate the patient's progress;

(8) Initial phases of a regimen involving administration of medical gases;

(9) Rehabilitation nursing procedures, including the related teaching and adaptive aspects of nursing, that are part of active treatment, e.g., the institution and supervision of bowel and bladder training programs.

(c) *Services which would qualify as skilled rehabilitation services.* (1) Ongoing assessment of rehabilitation needs and potential: Services concurrent with the management of a patient care plan, including tests and measurements of range of motion, strength, balance, coordination, endurance, functional ability, activities of daily living, perceptual deficits, speech and language or hearing disorders;

(2) Therapeutic exercises or activities: Therapeutic exercises or activities which, because of the type of exercises employed or the condition of the patient, must be performed by or under the supervision of a qualified physical therapist or occupational therapist to ensure the safety of the patient and the effectiveness of the treatment;

(3) Gait evaluation and training: Gait evaluation and training furnished to restore function in a patient whose ability to walk has been impaired by

neurological, muscular, or skeletal abnormality;

(4) Range of motion exercises: Range of motion exercises which are part of the active treatment of a specific disease state which has resulted in a loss of, or restriction of, mobility (as evidenced by a therapist's notes showing the degree of motion lost and the degree to be restored);

(5) Maintenance therapy; Maintenance therapy, when the specialized knowledge and judgment of a qualified therapist is required to design and establish a maintenance program based on an initial evaluation and periodic reassessment of the patient's needs, and consistent with the patient's capacity and tolerance. For example, a patient with Parkinson's disease who has not been under a rehabilitation regimen may require the services of a qualified therapist to determine what type of exercises will contribute the most to the maintenance of his present level of functioning.

(6) Ultrasound, short-wave, and microwave therapy treatment by a qualified physical therapist;

(7) Hot pack, hydrocollator, infrared treatments, paraffin baths, and whirlpool; Hot pack hydrocollator, infrared treatments, paraffin baths, and whirlpool in particular cases where the patient's condition is complicated by circulatory deficiency, areas of desensitization, open wounds, fractures, or other complications, and the skills, knowledge, and judgment of a qualified physical therapist are required; and

(8) Services of a speech pathologist or audiologist when necessary for the restoration of function in speech or hearing.

(d) *Personal care services.* Personal care services which do not require the skills of qualified technical or professional personnel are not skilled services except under the circumstances specified in § 409.32(b). Personal care services include, but are not limited to, the following:

(1) Administration of routine oral medications, eye drops, and ointments;

(2) General maintenance care of colostomy and ileostomy;

(3) Routine services to maintain satisfactory functioning of indwelling bladder catheters;

(4) Changes of dressings for noninfected postoperative or chronic conditions;

(5) Prophylactic and palliative skin care, including bathing and application of creams, or treatment of minor skin problems;

(6) Routine care of the incontinent patient, including use of diapers and protective sheets;

(7) General maintenance care in connection with a plaster cast;

(8) Routine care in connection with braces and similar devices;

(9) Use of heat as a palliative and comfort measure, such as whirlpool and hydrocollator;

(10) Routine administration of medical gases after a regimen of therapy has been established;

(11) Assistance in dressing, eating, and going to the toilet;

(12) Periodic turning and positioning in bed; and

(13) General supervision of exercises which have been taught to the patient; including the actual carrying out of maintenance programs, i.e., the performance of the repetitive exercises required to maintain function do not require the skills of a therapist and would not constitute skilled rehabilitation services (see paragraph (c) of this section). Similarly, repetitious exercises to improve gait, maintain strength, or endurance; passive exercises to maintain range of motion in paralyzed extremities, which are not related to a specific loss of function; and assistive walking do not constitute skilled rehabilitation services.

[48 FR 12541, Mar. 25, 1983, as amended at 63 FR 26307, May 12, 1998; 64 FR 41681, July 30, 1999]

§ 409.34 Criteria for "daily basis".

(a) To meet the daily basis requirement specified in § 409.31(b)(1), the following frequency is required:

(1) Skilled nursing services or skilled rehabilitation services must be needed and provided 7 days a week; or

(2) As an exception, if skilled rehabilitation services are not available 7 days a week those services must be needed and provided at least 5 days a week.

(b) A break of one or two days in the furnishing of rehabilitation services

will not preclude coverage if discharge would not be practical for the one or two days during which, for instance, the physician has suspended the therapy sessions because the patient exhibited extreme fatigue.

§ 409.35 Criteria for "practical matter".

(a) *General considerations.* In making a ''practical matter'' determination, as required by § 409.31(b)(3), consideration must be given to the patient's condition and to the availability and feasibility of using more economical alternative facilities and services. However, in making that determination, the availability of Medicare payment for those services may not be a factor. Example: The beneficiary can obtain daily physical therapy from a physical therapist in independent practice. However, Medicare pays only the appropriate portion (after deduction of applicable deductible and coinsurance amounts) of the first $500 of services furnished by such a practitioner in a year. This limitation on payment may not be a basis for finding that the needed care can only be provided in a SNF.

(b) *Examples of circumstances that meet practical matter criteria.* (1) *Beneficiary's condition.* Inpatient care would be required ''as a practical matter'' if transporting the beneficiary to and from the nearest facility that furnishes the required daily skilled services would be an excessive physical hardship.

(2) *Economy and efficiency.* Even if the beneficiary's condition does not preclude transportation, inpatient care might be more efficient and less costly if, for instance, the only alternative is daily transportation by ambulance.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 409.36 Effect of discharge from posthospital SNF care.

If a beneficiary is discharged from a facility after receiving posthospital SNF care, he or she is not entitled to additional services of this kind in the same benefit period unless—

(a) He or she is readmitted to the same or another facility within 30 calendar days following the day of discharge (or, before December 5, 1980, within 14 calendar days after discharge); or

(b) He or she is again hospitalized for at least 3 consecutive calendar days.

Subpart E—Home Health Services Under Hospital Insurance

§ 409.40 Basis, purpose, and scope.

This subpart implements sections 1814(a)(2)(C), 1835(a)(2)(A), and 1861(m) of the Act with respect to the requirements that must be met for Medicare payment to be made for home health services furnished to eligible beneficiaries.

[59 FR 65493, Dec. 20, 1994]

§ 409.41 Requirement for payment.

In order for home health services to qualify for payment under the Medicare program the following requirements must be met:

(a) The services must be furnished to an eligible beneficiary by, or under arrangements with, an HHA that—

(1) Meets the conditions of participation for HHAs at part 484 of this chapter; and

(2) Has in effect a Medicare provider agreement as described in part 489, subparts A, B, C, D, and E of this chapter.

(b) The physician certification and recertification requirements for home health services described in § 424.22.

(c) All requirements contained in §§ 409.42 through 409.47.

[59 FR 65494, Dec. 20, 1994]

§ 409.42 Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home health services, a beneficiary must meet each of the following requirements:

(a) *Confined to the home.* The beneficiary must be confined to the home or in an institution that is not a hospital, SNF or nursing facility as defined in section 1861(e)(1), 1819(a)(1) or 1919(a)(1) of the Act, respectively.

(b) *Under the care of a physician.* The beneficiary must be under the care of a physician who establishes the plan of care. A doctor of podiatric medicine may establish a plan of care only if that is consistent with the functions he or she is authorized to perform under State law.

(c) *In need of skilled services*. The beneficiary must need at least one of the following skilled services as certified by a physician in accordance with the physician certification and recertification requirements for home health services under § 424.22 of this chapter.

(1) Intermittent skilled nursing services that meet the criteria for skilled services and the need for skilled services found in § 409.32. (Also see § 409.33(a) and (b) for a description of examples of skilled nursing and rehabilitation services.)

(2) Physical therapy services that meet the requirements of § 409.44(c).

(3) Speech-language pathology services that meet the requirements of § 409.44(c).

(4) Continuing occupational therapy services that meet the requirements of § 409.44(c) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period.

(d) *Under a plan of care*. The beneficiary must be under a plan of care that meets the requirements for plans of care specified in § 409.43.

(e) *By whom the services must be furnished*. The home health services must be furnished by, or under arrangements made by, a participating HHA.

[59 FR 65494, Dec. 20, 1994; 60 FR 39122, Aug. 1, 1995]

§ 409.43 Plan of care requirements.

(a) *Contents*. The plan of care must contain those items listed in § 484.18(a) of this chapter that specify the standards relating to a plan of care that an HHA must meet in order to participate in the Medicare program.

(b) *Physician's orders*. The physician's orders for services in the plan of care must specify the medical treatments to be furnished as well as the type of home health discipline that will furnish the ordered services and at what frequency the services will be furnished. Orders for services to be provided ''as needed'' or ''PRN'' must be accompanied by a description of the beneficiary's medical signs and symptoms that would occasion the visit and a specific limit on the number of those visits to be made under the order before an additional physician order would have to be obtained. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished. If a range of visits is ordered, the upper limit of the range is considered the specific frequency.

(c) *Physician signature*. (1) *Request for Anticipated payment signature requirements*. If the physician signed plan of care is not available at the time the HHA requests an anticipated payment of the initial percentage prospective payment in accordance with § 484.205, the request for the anticipated payment must be based on—

(i) A physician's verbal order that—

(A) Is recorded in the plan of care;

(B) Includes a description of the patient's condition and the services to be provided by the home health agency;

(C) Includes an attestation (relating to the physician's orders and the date received) signed and dated by the registered nurse or qualified therapist (as defined in 42 CFR 484.4) responsible for furnishing or supervising the ordered service in the plan of care; and

(D) Is copied into the plan of care and the plan of care is immediately submitted to the physician; or

(ii) A referral prescribing detailed orders for the services to be rendered that is signed and dated by a physician.

(2) *Reduction or disapproval of anticipated payment requests*. CMS has the authority to reduce or disapprove requests for anticipated payments in situations when protecting Medicare program integrity warrants this action. Since the request for anticipated payment is based on verbal orders as specified in paragraph (c)(1)(i) and/or a prescribing referral as specified in (c)(1)(ii) of this section and is not a Medicare claim for purposes of the Act (although it is a ''claim'' for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a–7a (i) (2)), the Civil False Claims Act (as defined in 31 U.S.C. 3729(c)), and the Criminal False Claims Act (18 U.S.C. 287)), the request for anticipated payment will be canceled and recovered unless the claim is submitted

within the greater of 60 days from the end of the episode or 60 days from the issuance of the request for anticipated payment.

(3) *Final percentage payment signature requirements.* The plan of care must be signed and dated—

(i) By a physician as described who meets the certification and recertification requirements of § 424.22 of this chapter; and

(ii) Before the claim for each episode for services is submitted for the final percentage prospective payment.

(4) *Changes to the plan of care signature requirements.* Any changes in the plan must be signed and dated by a physician.

(d) *Oral (verbal) orders.* If any services are provided based on a physician's oral orders, the orders must be put in writing and be signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in § 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Oral orders may only be accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies. The oral orders must also be countersigned and dated by the physician before the HHA bills for the care.

(e) *Frequency of review.* (1) The plan of care must be reviewed by the physician (as specified in § 409.42(b)) in consultation with agency professional personnel at least every 60 days or more frequently when there is a—

(i) Beneficiary elected transfer;

(ii) Significant change in condition resulting in a change in the case-mix assignment; or

(iii) Discharge and return to the same HHA during the 60-day episode.

(2) Each review of a beneficiary's plan of care must contain the signature of the physician who reviewed it and the date of review.

(f) *Termination of the plan of care.* The plan of care is considered to be terminated if the beneficiary does not receive at least one covered skilled nursing, physical therapy, speech-language pathology services, or occupational therapy visit in a 60-day period unless the physician documents that the interval without such care is appropriate to the treatment of the beneficiary's illness or injury.

[59 FR 65494, Dec. 20, 1994, as amended at 65 FR 41210, July 3, 2000]

§ 409.44 Skilled services requirements.

(a) *General.* The intermediary's decision on whether care is reasonable and necessary is based on information provided on the forms and in the medical record concerning the unique medical condition of the individual beneficiary. A coverage denial is not made solely on the basis of the reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary's individual need for care.

(b) *Skilled nursing care.* (1) Skilled nursing care consists of those services that must, under State law, be performed by a registered nurse, or practical (vocational) nurse, as defined in § 484.4 of this chapter, and meet the criteria for skilled nursing services specified in § 409.32. See § 409.33(a) and (b) for a description of skilled nursing services and examples of them.

(i) In determining whether a service requires the skill of a licensed nurse, consideration must be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice.

(ii) If the nature of a service is such that it can safely and effectively be performed by the average nonmedical person without direct supervision of a licensed nurse, the service cannot be regarded as a skilled nursing service.

(iii) The fact that a skilled nursing service can be or is taught to the beneficiary or to the beneficiary's family or friends does not negate the skilled aspect of the service when performed by the nurse.

(iv) If the service could be performed by the average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.

(2) The skilled nursing care must be provided on a part-time or intermittent basis.

(3) The skilled nursing services must be reasonable and necessary for the treatment of the illness or injury.

(i) To be considered reasonable and necessary, the services must be consistent with the nature and severity of the beneficiary's illness or injury, his or her particular medical needs, and accepted standards of medical and nursing practice.

(ii) The skilled nursing care provided to the beneficiary must be reasonable within the context of the beneficiary's condition.

(iii) The determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time.

(c) *Physical therapy, speech-language pathology services, and occupational therapy*. To be covered, physical therapy, speech-language pathology services, and occupational therapy must satisfy the criteria in paragraphs (c)(1) through (4) of this section. Occupational therapy services initially qualify for home health coverage only if they are part of a plan of care that also includes intermittent skilled nursing care, physical therapy, or speech-language pathology services as follows:

(1) Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen (established by the physician, after any needed consultation with the qualified therapist) that is designed to treat the beneficiary's illness or injury. Services related to activities for the general physical welfare of beneficiaries (for example, exercises to promote overall fitness) do not constitute physical therapy, occupational therapy, or speech-language pathology services for Medicare purposes.

(2) Physical and occupational therapy and speech-language pathology services must be reasonable and necessary. To be considered reasonable and necessary, the following conditions must be met:

(i) The services must be considered under accepted standards of medical practice to be a specific, safe, and effective treatment for the beneficiary's condition.

(ii) The services must be of such a level of complexity and sophistication or the condition of the beneficiary must be such that the services required can safely and effectively be performed only by a qualified physical therapist or by a qualified physical therapy assistant under the supervision of a qualified physical therapist, by a qualified speech-language pathologist, or by a qualified occupational therapist or a qualified occupational therapy assistant under the supervision of a qualified occupational therapist (as defined in § 484.4 of this chapter). Services that do not require the performance or supervision of a physical therapist or an occupational therapist are not considered reasonable or necessary physical therapy or occupational therapy services, even if they are performed by or supervised by a physical therapist or occupational therapist. Services that do not require the skills of a speech-language pathologist are not considered to be reasonable and necessary speech-language pathology services even if they are performed by or supervised by a speech-language pathologist.

(iii) There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and unique medical condition, or the services must be necessary to establish a safe and effective maintenance program required in connection with a specific disease, or the skills of a therapist must be necessary to perform a safe and effective maintenance program. If the services are for the establishment of a maintenance program, they may include the design of the program, the instruction of the beneficiary, family, or home health aides, and the necessary infrequent reevaluations of the beneficiary and the program to the degree that the specialized knowledge and judgment of a physical therapist, speech-language pathologist, or occupational therapist is required.

(iv) The amount, frequency, and duration of the services must be reasonable.

[59 FR 65494, Dec. 20, 1994]

§ 409.45 Dependent services requirements.

(a) *General.* Services discussed in paragraphs (b) through (g) of this section may be covered only if the beneficiary needs skilled nursing care on an intermittent basis, as described in § 409.44(b); physical therapy or speech-language pathology services as described in § 409.44(c); or has a continuing need for occupational therapy services as described in § 409.44(c) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period; and otherwise meets the qualifying criteria (confined to the home, under the care of a physician, in need of skilled services, and under a plan of care) specified in § 409.42. Home health coverage is not available for services furnished to a beneficiary who is no longer in need of one of the qualifying skilled services specified in this paragraph. Therefore, dependent services furnished after the final qualifying skilled service are not covered, except when the dependent service was not followed by a qualifying skilled service as a result of the unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event.

(b) *Home health aide services.* To be covered, home health aide services must meet each of the following requirements:

(1) The reason for the visits by the home health aide must be to provide hands-on personal care to the beneficiary or services that are needed to maintain the beneficiary's health or to facilitate treatment of the beneficiary's illness or injury. The physician's order must indicate the frequency of the home health aide services required by the beneficiary. These services may include but are not limited to:

(i) Personal care services such as bathing, dressing, grooming, caring for hair, nail and oral hygiene that are needed to facilitate treatment or to prevent deterioration of the beneficiary's health, changing the bed linens of an incontinent beneficiary, shaving, deodorant application, skin care with lotions and/or powder, foot care, ear care, feeding, assistance with elimination (including enemas unless the skills of a licensed nurse are required due to the beneficiary's condition, routine catheter care, and routine colostomy care), assistance with ambulation, changing position in bed, and assistance with transfers.

(ii) Simple dressing changes that do not require the skills of a licensed nurse.

(iii) Assistance with medications that are ordinarily self-administered and that do not require the skills of a licensed nurse to be provided safely and effectively.

(iv) Assistance with activities that are directly supportive of skilled therapy services but do not require the skills of a therapist to be safely and effectively performed, such as routine maintenance exercises and repetitive practice of functional communication skills to support speech-language pathology services.

(v) Routine care of prosthetic and orthotic devices.

(2) The services to be provided by the home health aide must be—

(i) Ordered by a physician in the plan of care; and

(ii) Provided by the home health aide on a part-time or intermittent basis.

(3) The services provided by the home health aide must be reasonable and necessary. To be considered reasonable and necessary, the services must—

(i) Meet the requirement for home health aide services in paragraph (b)(1) of this section;

(ii) Be of a type the beneficiary cannot perform for himself or herself; and

(iii) Be of a type that there is no able or willing caregiver to provide, or, if there is a potential caregiver, the beneficiary is unwilling to use the services of that individual.

(4) The home health aide also may perform services incidental to a visit that was for the provision of care as described in paragraphs (b)(3)(i) through (iii) of this section. For example, these incidental services may include changing bed linens, personal laundry, or preparing a light meal.

(c) *Medical social services*. Medical social services may be covered if the following requirements are met:

(1) The services are ordered by a physician and included in the plan of care.

(2)(i) The services are necessary to resolve social or emotional problems that are expected to be an impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(ii) If these services are furnished to a beneficiary's family member or caregiver, they are furnished on a short-term basis and it can be demonstrated that the service is necessary to resolve a clear and direct impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(3) The frequency and nature of the medical social services are reasonable and necessary to the treatment of the beneficiary's condition.

(4) The medical social services are furnished by a qualified social worker or qualified social work assistant under the supervision of a social worker as defined in § 484.4 of this chapter.

(5) The services needed to resolve the problems that are impeding the beneficiary's recovery require the skills of a social worker or a social work assistant under the supervision of a social worker to be performed safely and effectively.

(d) *Occupational therapy*. Occupational therapy services that are not qualifying services under § 409.44(c) are nevertheless covered as dependent services if the requirements of § 409.44(c)(2)(i) through (iv), as to reasonableness and necessity, are met.

(e) *Durable medical equipment*. Durable medical equipment in accordance with § 410.38 of this chapter, which describes the scope and conditions of payment for durable medical equipment under Part B, may be covered under the home health benefit as either a Part A or Part B service. Durable medical equipment furnished by an HHA as a home health service is always covered by Part A if the beneficiary is entitled to Part A.

(f) *Medical supplies*. Medical supplies (including catheters, catheter supplies, ostomy bags, and supplies relating to ostomy care but excluding drugs and biologicals) may be covered as a home health benefit. For medical supplies to be covered as a Medicare home health benefit, the medical supplies must be needed to treat the beneficiary's illness or injury that occasioned the home health care.

(g) *Intern and resident services*. The medical services of interns and residents in training under an approved hospital teaching program are covered if the services are ordered by the physician who is responsible for the plan of care and the HHA is affiliated with or under the common control of the hospital furnishing the medical services.

Approved means—

(1) Approved by the Accreditation Council for Graduate Medical Education;

(2) In the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association;

(3) In the case of an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American Dental Association; or

(4) In the case of an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association.

[59 FR 65495, Dec. 20, 1994; 60 FR 39122, 39123, Aug. 1, 1995]

§ 409.46 Allowable administrative costs.

Services that are allowable as administrative costs but are not separately billable include, but are not limited to, the following:

(a) *Registered nurse initial evaluation visits*. Initial evaluation visits by a registered nurse for the purpose of assessing a beneficiary's health needs, determining if the agency can meet those health needs, and formulating a plan of care for the beneficiary are allowable administrative costs. If a physician specifically orders that a particular skilled service be furnished during the evaluation in which the agency accepts the beneficiary for treatment and all other coverage criteria are met, the visit is billable as a skilled nursing

visit. Otherwise it is considered to be an administrative cost.

(b) *Visits by registered nurses or qualified professionals for the supervision of home health aides.* Visits by registered nurses or qualified professionals for the purpose of supervising home health aides as required at § 484.36(d) of this chapter are allowable administrative costs. Only if the registered nurse or qualified professional visits the beneficiary for the purpose of furnishing care that meets the coverage criteria at § 409.44, and the supervisory visit occurs simultaneously with the provision of covered care, is the visit billable as a skilled nursing or therapist's visit.

(c) *Respiratory care services.* If a respiratory therapist is used to furnish overall training or consultative advice to an HHA's staff and incidentally provides respiratory therapy services to beneficiaries in their homes, the costs of the respiratory therapist's services are allowable as administrative costs. Visits by a respiratory therapist to a beneficiary's home are not separately billable. However, respiratory therapy services that are furnished as part of a plan of care by a skilled nurse or physical therapist and that constitute skilled care may be separately billed as skilled visits.

(d) *Dietary and nutrition personnel.* If dieticians or nutritionists are used to provide overall training or consultative advice to HHA staff and incidentally provide dietetic or nutritional services to beneficiaries in their homes, the costs of these professional services are allowable as administrative costs. Visits by a dietician or nutritionist to a beneficiary's home are not separately billable.

[59 FR 65496, Dec. 20, 1994]

§ 409.47 Place of service requirements.

To be covered, home health services must be furnished in either the beneficiary's home or an outpatient setting as defined in this section.

(a) *Beneficiary's home.* A beneficiary's home is any place in which a beneficiary resides that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1), of 1919(a)(1) of the Act, respectively.

(b) *Outpatient setting.* For purposes of coverage of home health services, an outpatient setting may include a hospital, SNF or a rehabilitation center with which the HHA has an arrangement in accordance with the requirements of § 484.14(h) of this chapter and that is used by the HHA to provide services that either—

(1) Require equipment that cannot be made available at the beneficiary's home; or

(2) Are furnished while the beneficiary is at the facility to receive services requiring equipment described in paragraph (b)(1) of this section.

[59 FR 65496, Dec. 20, 1994]

§ 409.48 Visits.

(a) *Number of allowable visits under Part A.* To the extent that all coverage requirements specified in this subpart are met, payment may be made on behalf of eligible beneficiaries under Part A for an unlimited number of covered home health visits. All Medicare home health services are covered under hospital insurance unless there is no Part A entitlement.

(b) *Number of visits under Part B.* To the extent that all coverage requirements specified in this subpart are met, payment may be made on behalf of eligible beneficiaries under Part B for an unlimited number of covered home health visits. Medicare home health services are covered under Part B only when the beneficiary is not entitled to coverage under Part A.

(c) *Definition of visit.* A visit is an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA, for the purpose of providing a covered service.

(1) Generally, one visit may be covered each time an HHA employee or someone providing home health services under arrangements enters the beneficiary's home and provides a covered service to a beneficiary who meets the criteria of § 409.42 (confined to the home, under the care of a physician, in need of skilled services, and under a plan of care).

(2) If the HHA furnishes services in an outpatient facility under arrangements with the facility, one visit may be covered for each type of service provided.

(3) If two individuals are needed to provide a service, two visits may be covered. If two individuals are present, but only one is needed to provide the care, only one visit may be covered.

(4) A visit is initiated with the delivery of covered home health services and ends at the conclusion of delivery of covered home health services. In those circumstances in which all reasonable and necessary home health services cannot be provided in the course of a single visit, HHA staff or others providing services under arrangements with the HHA may remain at the beneficiary's residence between visits (for example, to provide non-covered services). However, if all covered services could be provided in the course of one visit, only one visit may be covered.

[59 FR 65497, Dec. 20, 1994]

§ 409.49 Excluded services.

(a) *Drugs and biologicals*. Drugs and biologicals are excluded from payment under the Medicare home health benefit.

(1) A drug is any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other condition or for the relief of pain or suffering or to control or improve any physiological pathologic condition.

(2) A biological is any medicinal preparation made from living organisms and their products including, but not limited to, serums, vaccines, antigens, and antitoxins.

(b) *Transportation*. The transportation of beneficiaries, whether to receive covered care or for other purposes, is excluded from home health coverage. Costs of transportation of equipment, materials, supplies, or staff may be allowable as administrative costs, but no separate payment is made for them.

(c) *Services that would not be covered as inpatient services*. Services that would not be covered if furnished as inpatient hospital services are excluded from home health coverage.

(d) *Housekeeping services*. Services whose sole purpose is to enable the beneficiary to continue residing in his or her home (for example, cooking, shopping, Meals on Wheels, cleaning, laundry) are excluded from home health coverage.

(e) *Services covered under the End Stage Renal Disease (ESRD) program*. Services that are covered under the ESRD program and are contained in the composite rate reimbursement methodology, including any service furnished to a Medicare ESRD beneficiary that is directly related to that individual's dialysis, are excluded from coverage under the Medicare home health benefit.

(f) *Prosthetic devices*. Items that meet the requirements of § 410.36(a)(2) of this chapter for prosthetic devices covered under Part B are excluded from home health coverage. Catheters, catheter supplies, ostomy bags, and supplies relating to ostomy care are not considered prosthetic devices if furnished under a home health plan of care and are not subject to this exclusion from coverage.

(g) *Medical social services provided to family members*. Except as provided in § 409.45(c)(2), medical social services provided solely to members of the beneficiary's family and that are not incidental to covered medical social services being provided to the beneficiary are not covered.

[59 FR 65497, Dec. 20, 1994; 60 FR 39123, Aug. 1, 1995]

§ 409.50 Coinsurance for durable medical equipment (DME) furnished as a home health service.

The coinsurance liability of the beneficiary or other person for DME furnished as a home health service is 20 percent of the customary (insofar as reasonable) charge for the services.

[51 FR 41339, Nov. 14, 1986. Redesignated at 59 FR 65496, Dec. 20, 1994]

Subpart F—Scope of Hospital Insurance Benefits

§ 409.60 Benefit periods.

(a) *When benefit periods begin*. The initial benefit period begins on the day the beneficiary receives inpatient hospital, inpatient CAH, or SNF services for the first time after becoming entitled to hospital insurance. Thereafter, a new benefit period begins whenever

the beneficiary receives inpatient hospital, inpatient CAH, or SNF services after he or she has ended a benefit period as described in paragraph (b) of this section.

(b) *When benefit periods end*—(1) A benefit period ends when a beneficiary has, for at least 60 consecutive days not been an inpatient in any of the following:

(i) A hospital that meets the requirements of section 1861(e)(1) of the Act.

(ii) A CAH that meets the requirements of section 1820 of the Act.

(iii) A SNF that meets the requirements of sections 1819(a)(1) or 1861(y) of the Act.

(2) For purposes of ending a benefit period, a beneficiary was an inpatient of a SNF if his or her care in the SNF met the skilled level of care requirements specified in § 409.31(b) (1) and (3).

(c) *Presumptions.* (1) For purposes of determining whether a beneficiary was an inpatient of a SNF under paragraph (b)(2) of this section—

(i) A beneficiary's care met the skilled level of care requirements if inpatient SNF claims were paid for those services under Medicare or Medicaid, unless:

(A) Such payments were made under § 411.400 or Medicaid administratively necessary days provisions which result in payment for care not meeting the skilled level of care requirements, or

(B) A Medicare denial and a Medicaid payment are made for the same period, in which case the presumption in paragraph (c)(2)(ii) of this section applies;

(ii) A beneficiary's care met the skilled level of care requirements if a SNF claim was paid under section 1879(e) of the Social Security Act;

(iii) A beneficiary's care did not meet the skilled level of care requirements if a SNF claim was paid for the services under § 411.400;

(iv) A beneficiary's care did not meet the skilled level of care requirements if a Medicaid SNF claim was denied on the grounds that the services were not at the skilled level of care (even if paid under applicable Medicaid administratively necessary days provisions which result in payment for care not meeting the skilled level of care requirements);

(2) For purposes of determining whether a beneficiary was an inpatient of a SNF under paragraph (b)(2) of this section a beneficiary's care in a SNF is presumed—

(i) To have met the skilled level of care requirements during any period for which the beneficiary was assigned to one of the Resource Utilization Groups designated as representing the required level of care, as provided in § 409.30.

(ii) To have met the skilled level of care requirements if a Medicaid or Medicare claim was denied on grounds other than that the services were not at the skilled level of care;

(iii) Not to have met the skilled level of care requirements if a Medicare SNF claim was denied on the grounds that the services were not at the skilled level of care and payment was not made under § 411.400; or

(iv) Not to have met the skilled level of care requirements if no Medicare or Medicaid claim was submitted by the SNF.

(3) If information upon which to base a presumption is not readily available, the intermediary may, at its discretion review the beneficiary's medical records to determine whether he or she was an inpatient of a SNF as set forth under paragraph (b)(2) of this section.

(4) When the intermediary makes a benefit period determination based upon paragraph (c)(1) of this section, the beneficiary may seek to reverse the benefit period determination by timely appealing the prior Medicare SNF claim determination under part 405, subpart G of this chapter, or the prior Medicaid SNF claim under part 431, subpart E of this chapter.

(5) When the intermediary makes a benefit period determination under paragraph (c)(2) of this section, the beneficiary will be notified of the basis for the determination, and of his or her right to present evidence to rebut the determination that the skilled level of care requirements specified in § 409.31 (b)(1) and (b)(3) were or were not met on reconsideration and appeal under 42 CFR, part 405, subpart G of this chapter.

(d) *Limitation on benefit period determinations.* When the intermediary considers the same prior SNF stay of a

particular beneficiary in making benefit period determinations for more than one inpatient Medicare claim—

(1) Medicare will recognize only the initial level of care characterization for that prior SNF stay (or if appealed under 42 CFR part 405, subpart G of this chapter, the level of care determined under appeal); or

(2) If part of a prior SNF stay has one level of care characterization and another part has another level of care characterization, Medicare will recognize only the initial level of care characterization for a particular part of a prior SNF stay (or if appealed under 42 CFR part 405, subpart G of this chapter, the level of care determined under appeal).

(e) *Relation of benefit period to benefit limitations.* The limitations specified in §§ 409.61 and 409.64, and the deductible and coinsurance requirements set forth in subpart G of this part apply for each benefit period. The limitations of § 409.63 apply only to the initial benefit period.

[52 FR 22645, June 15, 1987; 52 FR 28824, Aug. 4, 1987, as amended at 58 FR 30667, May 26, 1993; 63 FR 26307, May 12, 1998; 70 FR 45055, Aug. 4, 2005]

§ 409.61 General limitations on amount of benefits.

(a) *Inpatient hospital or inpatient CAH services.* (1) *Regular benefit days.* Up to 90 days are available in each benefit period, subject to the limitations on days for psychiatric hospital services set forth in §§ 409.62 and 409.63.

(i) For the first 60 days (referred to in this subpart as *full benefit days*), Medicare pays the hospital or CAH for all covered services furnished the beneficiary, except for a deductible which is the beneficiary's responsibility. (Section 409.82 specifies the requirements for the inpatient hospital deductible.)

(ii) For the next 30 days (referred to in this subpart as *coinsurance days*), Medicare pays for all covered services except for a daily coinsurance amount, which is the beneficiary's responsibility. (Section 409.83 specifies the inpatient hospital coinsurance amounts.)

(2) *Lifetime reserve days.* Each beneficiary has a non-renewable lifetime reserve of 60 days of inpatient hospital or inpatient CAH services that he may draw upon whenever he is hospitalized for more than 90 days in a benefit period. Upon exhaustion of the regular benefit days, the reserve days will be used unless the beneficiary elects not to use them, as provided in § 409.65. For lifetime reserve days, Medicare pays for all covered services except for a daily coinsurance amount that is the beneficiary's responsibility. (See § 409.83.)

(3) *Order of payment for inpatient hospital or inpatient CAH services.* Medicare pays for inpatient hospital services in the following order.

(i) The 60 full benefit days;

(ii) The 30 coinsurance days;

(iii) The remaining lifetime reserve days.

(b) *Posthospital SNF care furnished by a SNF, or by a hospital or a CAH with a swing-bed approval.* Up to 100 days are available in each benefit period after discharge from a hospital or CAH. For the first 20 days, Medicare pays for all covered services. For the 21st through 100th day, Medicare pays for all covered services except for a daily coinsurance amount that is the beneficiary's responsibility.

(c) *Renewal of inpatient benefits.* The beneficiary's full entitlement to the 90 inpatient hospital or inpatient CAH regular benefit days, and the 100 SNF benefit days, is renewed each time he or she begins a benefit period. However, once lifetime reserve days are used, they can never be renewed.

(d) *Home health services.* Medicare Part A pays for all covered home health services[1] with no deductible, and subject to the following limitations on payment for durable medical equipment (DME):

(1) For DME furnished by an HHA that is a nominal charge provider, Medicare Part A pays 80 percent of fair compensation.

(2) For DME furnished by an HHA that is not a nominal charge provider, Medicare Part A pays the lesser of the following:

(i) 80 percent of the reasonable cost of the service.

[1] Before July 1, 1981, Medicare Part A paid for not more than 100 home health visits during one year following the beneficiary's most recent discharge from a hospital or a SNF.

(ii) The reasonable cost of, or the customary charge for, the service, whichever is less, minus 20 percent of the customary (insofar as reasonable) charge for the service.

[48 FR 12541, Mar. 25, 1983, as amended at 51 FR 41339, Nov. 14, 1986; 54 FR 4027, Jan. 27, 1989; 58 FR 30666, 30667, May 26, 1993]

§ 409.62 Lifetime maximum on inpatient psychiatric care.

There is a lifetime maximum of 190 days on inpatient psychiatric hospital services available to any beneficiary. Therefore, once an individual receives benefits for 190 days of care in a psychiatric hospital, no further benefits of that type are available to that individual.

§ 409.63 Reduction of inpatient psychiatric benefit days available in the initial benefit period.

(a) *Reduction rule.* (1) If the individual was an inpatient in a psychiatric hospital on the first day of Medicare entitlement and for any of the 150 days immediately before that first day of entitlement, those days are subtracted from the 150 days (90 regular days plus 60 lifetime reserve days) which would otherwise be available in the initial benefit period for inpatient psychiatric services in a psychiatric or general hospital.

(2) Reduction is required only if the hospital was participating in Medicare as a psychiatric hospital on the individual's first day of entitlement.

(3) The reduction applies only to the beneficiary's first benefit period. For subsequent benefit periods, the 90 benefit days, plus any remaining lifetime reserve days, subject to the 190 day lifetime limit on psychiatric hospital care, are available.

(b) *Application to general hospital days.* (1) Days spent in a general hospital before entitlement are not subtracted under paragraph (a) of this section even if the stay was for diagnosis or treatment of mental illness.

(2) After entitlement, all psychiatric care days, whether in a general or a psychiatric hospital, are counted toward the number of days available in the initial benefit period.

(c) *Examples:* (1) The individual was an inpatient of a participating psychiatric hospital for 20 days before the first day of entitlement and remained there for another 6 months. Therefore, 130 days of benefits (150 minus 20) are payable. Payment could be made for: 60 full benefit days, 30 coinsurance days, and 40 lifetime reserve days.

(2) During the 150-day period preceding Medicare entitlement, an individual had been a patient of a general hospital for 60 days of inpatient psychiatric care and had spent 90 days in a psychiatric hospital, ending with the first day of entitlement. During the initial benefit period, the beneficiary spent 90 days in a general hospital and received psychiatric care there. The 60 days spent in the general hospital for psychiatric treatment before entitlement do not reduce the benefits available in the first benefit period. Only the 90 days spent in the psychiatric hospital before entitlement reduce such benefits, leaving a total of 60 available psychiatric days. However, after entitlement, the reduction applies not only to days spent in a psychiatric hospital, but also to days of psychiatric treatment in a general hospital. Thus, Medicare payment could be made only for 60 of the 90 days spent in the general hospital.

(3) An individual was admitted to a general hospital for a mental condition and, after 10 days, transferred to a participating psychiatric hospital. The individual remained in the psychiatric hospital for 78 days before becoming entitled to hospital insurance benefits and for 130 days after entitlement. The beneficiary was then transferred to a general hospital and received treatment of a medical condition for 20 days. The 10 days spent in the general hospital during the 150-day pre-entitlement period have no effect on the inpatient hospital benefit days available to the individual for psychiatric care in the first benefit period, even though the general hospital stay was for a mental condition. Only the 78 days spent in the psychiatric hospital during the pre-entitlement period are subtracted from the 150 benefit days. Accordingly, the individual has 72 days of psychiatric care (150 days less 78 days) available in the first benefit period. Benefits could be paid for the individual's hospitalization during the first

benefit period in the following manner. For the 130-day psychiatric hospital stay, 72 days (60 full benefit days and 12 coinsurance days), and for the general hospital stay, 20 days (18 coinsurance and 2 lifetime reserve days).

§ 409.64 Services that are counted toward allowable amounts.

(a) Except as provided in paragraph (b) of this section for lifetime reserve days, all covered inpatient days and home health visits are counted toward the allowable amounts specified in §§ 409.61 through 409.63 if—

(1) They are paid for by Medicare; or

(2) They would be paid for by Medicare if the following requirements had been met:

(i) A proper and timely request for payment had been filed; and

(ii) The hospital, CAH, SNF, or home health agency had submitted all necessary evidence, including physician certification of need for services when such certification was required; or

(3) They could not be paid for because the total payment due was equal to, or less than, the applicable deductible and coinsurance amounts.

(b) *Exception*. Even though the requirements of paragraph (a)(2) of this section are met, lifetime reserve days are not counted toward the allowable amounts if the beneficiary elected or is deemed to have elected not to use them as set forth in § 409.65.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30667, May 26, 1993]

§ 409.65 Lifetime reserve days.

(a) *Election not to use lifetime reserve days*. (1) Whenever a beneficiary has exhausted the 90 regular benefit days, the hospital or CAH may bill Medicare for lifetime reserve days unless the beneficiary elects not to use them or, in accordance with paragraph (b) of this section, is deemed to have elected not to use them.

(2) It may be advantageous to elect not to use lifetime reserve days if the beneficiary has private insurance coverage that begins after the first 90 inpatient days in a benefit period, or if the daily charge is only slightly higher than the lifetime reserve days coinsurance amount. In such cases, the beneficiary may want to save the lifetime reserve days for future care that may be more expensive.

(3) If the beneficiary elects not to use lifetime reserve days for a particular hospital or CAH stay, they are still available for a later stay. However, once the beneficiary uses lifetime reserve days, they can never be renewed.

(4) If the beneficiary elects not to use lifetime reserve days, the hospital or CAH may require him or her to pay for any services furnished after the regular days are exhausted.

(b) *Deemed election*. A beneficiary will be deemed to have elected not to use lifetime reserve days if the average daily charges for such days is equal to or less than the applicable coinsurance amount specified in § 409.83. A beneficiary would get no benefit from using the days under those circumstances.

(c) *Who may file an election*. An election not to use reserve days may be filed by—

(1) The beneficiary; or

(2) If the beneficiary is physically or mentally unable to act, by the beneficiary's legal representative. In addition, if some other payment source is available, such as private insurance, any person authorized under § 405.1664 of this chapter to execute a request for payment for the beneficiary may file the election.

(d) *Filing the election*. (1) The beneficiary's election not to use lifetime reserve days must be filed in writing with the hospital or CAH.

(2) The election may be filed at the time of admission to the hospital or CAH or at any time thereafter up to 90 days after the beneficiary's discharge.

(3) A retroactive election (that is, one made after lifetime reserve days have been used because the regular days were exhausted), is not acceptable unless it is approved by the hospital or CAH.

(e) *Period covered by election*—(1) *General rule*. Except as provided in paragraph (e)(2) of this section, an election not to use lifetime reserve days may apply to an entire hospital or CAH stay or to a single period of consecutive days in a stay, but cannot apply to selected days in a stay. For example, a beneficiary may restrict the election to the period covered by private insurance but cannot use individual lifetime

reserve days within that period. If an election not to use reserve days is effective after the first day on which reserve days are available, it must remain in effect until the end of the stay, unless it is revoked in accordance with § 409.66.

(2) *Exception*. A beneficiary election not to use lifetime reserve days for an inpatient hospital or inpatient CAH stay for which payment may be made under the prospective payment system (part 412 of this chapter) is subject to the following rules:

(i) If the beneficiary has one or more regular benefit days (see § 409.61(a)(1) of this chapter) remaining in the benefit period upon entering the hospital or CAH, an election not to use lifetime reserve days will apply automatically to all days that are not outlier days. The beneficiary may also elect not to use lifetime reserve days for outlier days but this election must apply to all outlier days.

(ii) If the beneficiary has no regular benefit days (see § 409.61(a)(1) of this chapter) remaining in the benefit period upon entering the hospital or CAH, an election not to use lifetime reserve days must apply to the entire hospital or CAH stay.

[48 FR 12541, Mar. 25, 1983, as amended at 48 FR 39837, Sept. 1, 1983; 49 FR 323, Jan. 3, 1984; 58 FR 30666, 30667, May 26, 1993]

§ 409.66 Revocation of election not to use lifetime reserve days.

(a) Except as provided in paragraph (c) of this section, a beneficiary (or anyone authorized to execute a request for payment, if the beneficiary is incapacitated) may revoke an election not to use lifetime reserve days during hospitalization or within 90 days after discharge.

(b) The revocation must be submitted to the hospital or CAH in writing and identify the stay or stays to which it applies.

(c) *Exceptions*. A revocation of an election not to use lifetime reserve days may not be filed—

(1) After the beneficiary dies; or

(2) After the hospital or CAH has filed a claim under the supplementary medical insurance program (Medicare Part B), for medical and other health services furnished to the beneficiary on the days in question.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.68 Guarantee of payment for inpatient hospital or inpatient CAH services furnished before notification of exhaustion of benefits.

(a) *Conditions for payment*. Payment may be made for inpatient hospital or inpatient CAH services furnished a beneficiary after he or she has exhausted the available benefit days if the following conditions are met:

(1) The services were furnished before CMS or the intermediary notified the hospital or CAH that the beneficiary had exhausted the available benefit days and was not entitled to have payment made for those services.

(2) At the time the hospital or CAH furnished the services, it was unaware that the beneficiary had exhausted the available benefit days and could reasonably have assumed that he or she was entitled to have payment made for these services.

(3) Payment would be precluded solely because the beneficiary has no benefit days available for the particular hospital or CAH stay.

(4) The hospital or CAH claims reimbursement for the services and refunds any payments made for those services by the beneficiary or by another person on his or her behalf.

(b) *Limitations on payment*. (1) If all of the conditions in paragraph (a) of this section are met, Medicare payment may be made for the day of admission, and up to 6 weekdays thereafter, plus any intervening Saturdays, Sundays, and Federal holidays.

(2) Payment may not be made under this section for any day after the hospital or CAH is notified that the beneficiary has exhausted the available benefit days.

(c) *Recovery from the beneficiary*. Any payment made to a hospital or CAH under this section is considered an overpayment to the beneficiary and may be recovered from him or her under the provisions set forth elsewhere in this chapter.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, May 26, 1993]

Subpart G—Hospital Insurance Deductibles and Coinsurance

§ 409.80 Inpatient deductible and coinsurance: General provisions.

(a) *What they are.* (1) The inpatient deductible and coinsurance amounts are portions of the cost of covered hospital or CAH or SNF services that Medicare does not pay.

(2) The hospital or CAH or SNF may charge these amounts to the beneficiary or someone on his or her behalf.

(b) *Changes in the inpatient deductible and coinsurance amounts.* (1) The law requires the Secretary to adjust the inpatient hospital deductible each year to reflect changes in the average cost of hospital care. In adjusting the deductible, the Secretary must use a formula specified in section 1813(b)(2) of the Act. Under that formula, the inpatient hospital deductible is increased each year by about the same percentage as the increase in the average Medicare daily hospital costs. The result of the deductible increase is that the beneficiary continues to pay about the same proportion of the hospital bill.

(2) Since the coinsurance amounts are, by statute, specific fractions of the deductible, they change when the deductible changes.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.82 Inpatient hospital deductible.

(a) *General provisions*—(1) The inpatient hospital deductible is a fixed amount chargeable to the beneficiary when he or she receives covered services in a hospital or a CAH for the first time in a benefit period.

(2) Although the beneficiary may be hospitalized several times during a benefit period, the deductible is charged only once during that period. If the beneficiary begins more than one benefit period in the same year, a deductible is charged for each of those periods.

(3) For services furnished before January 1, 1982, the applicable deductible is the one in effect when the benefit period began.

(4) For services furnished after December 31, 1981, the applicable deductible is the one in effect during the calendar year in which the services were furnished.

(b) *Specific deductible amounts.* The specific deductible amounts for each calendar year are published in the FEDERAL REGISTER no later than October 1 of the preceding year.

(c) *Exception to published amounts.* If the total hospital or CAH charge is less than the deductible amount applicable for the calendar year in which the services were furnished, the amount of the charge is the deductible for the year.

[48 FR 12541, Mar. 25, 1983, as amended at 54 FR 4026, Jan. 27, 1989; 58 FR 30666, 30667, May 26, 1993]

§ 409.83 Inpatient hospital coinsurance.

(a) *General provisions*—(1) Inpatient hospital coinsurance is the amount chargeable to a beneficiary for each day after the first 60 days of inpatient hospital care or inpatient CAH care or both in a benefit period.

(2) For each day from the 61st to the 90th day, the coinsurance amount is ¼ of the applicable deductible.

(3) For each day from the 91st to the 150th day (lifetime reserve days), the coinsurance amount is ½ of the applicable deductible.

(4) For coinsurance days before January 1, 1982, the coinsurance amount is based on the deductible applicable for the calendar year in which the benefit period began. The coinsurance amounts do not change during a beneficiary's benefit period even though the coinsurance days may fall in a subsequent year for which a higher deductible amount has been determined.

(5) For coinsurance days after December 31, 1981, the coinsurance amount is based on the deductible applicable for the calendar year in which the services were furnished. For example, if an individual starts a benefit period by being admitted to a hospital in 1981 and remains in the hospital long enough to use coinsurance days in 1982, the coinsurance amount charged for those days is based on the 1982 inpatient hospital deductible.

(b) *Specific coinsurance amounts.* The specific coinsurance amounts for each calendar year are published in the FEDERAL REGISTER no later than October 1 of the preceding year.

(c) *Exceptions to published amounts.* (1) If the actual charge to the patient for the 61st through the 90th day of inpatient hospital or inpatient CAH services is less than the coinsurance amount applicable for the calendar year in which the services were furnished, the actual charge per day is the daily coinsurance amount.

(2) If the actual charge to the patient for the 91st through the 150th day (lifetime reserve days) is less than the coinsurance amount applicable for the calendar year in which the services were furnished, the beneficiary is deemed to have elected not to use the days because he or she would not benefit from using them.

[48 FR 12541, Mar. 25, 1983, as amended at 54 FR 4026, Jan. 27, 1989; 58 FR 30666, 30667, May 26, 1993]

§ 409.85 Skilled nursing facility (SNF) care coinsurance.

(a) *General provisions.* (1) SNF care coinsurance is the amount chargeable to a beneficiary after the first 20 days of SNF care in a benefit period.

(2) For each day from the 21st through the 100th day, the coinsurance is ⅛ of the applicable inpatient hospital deductible.

(3) For coinsurance days before January 1, 1982, the coinsurance amount is based on the deductible applicable for the year in which the benefit period began. The coinsurance amounts do not change during a beneficiary's benefit period even though the coinsurance days may fall in a subsequent year for which a higher deductible amount has been determined.

(4) For coinsurance days after December 31, 1981, the coinsurance amount is based on the deductible applicable for the calendar year in which the services were furnished.

(b) *Specific coinsurance amounts.* The specific SNF coinsurance amounts for each calendar year are published in the FEDERAL REGISTER no later than October 1 of the preceding year.

(c) *Exception to published amounts.* If the actual charge to the patient is less than the coinsurance amount applicable for the calendar year in which the services were furnished, the actual charge per day is the daily coinsurance.

[48 FR 12541, Mar. 25, 1983, as amended at 54 FR 4026, Jan. 27, 1989]

§ 409.87 Blood deductible.

(a) *General provisions.* (1) As used in this section, packed red cells means the red blood cells that remain after plasma is separated from whole blood.

(2) A unit of packed red cells is treated as the equivalent of a unit of whole blood.

(3) Medicare does not pay for the first 3 units of whole blood or units of packed red cells that a beneficiary receives, during a calendar year, as an inpatient of a hospital or CAH or SNF, or on an outpatient basis under Medicare Part B.

(4) The deductible does not apply to other blood components such as platelets, fibrinogen, plasma, gamma globulin, and serum albumin, or to the cost of processing, storing, and administering blood.

(5) The blood deductible is in addition to the inpatient hospital deductible and daily coinsurance.

(6) The Part A blood deductible is reduced to the extent that the Part B blood deductible has been applied. For example, if a beneficiary had received one unit under Medicare Part B, and later in the same benefit period received three units under Medicare Part A, Medicare Part A would pay for the third of the latter units. (As specified in § 410.161 of this chapter, the Part B blood deductible is reduced to the extent a blood deductible has been applied under Medicare Part A.)

(b) *Beneficiary's responsibility for the first 3 units of whole blood or packed red cells.* (1) *Basic rule.* Except as specified in paragraph (b)(2) of this section, the beneficiary is responsible for the first 3 units of whole blood or packed red cells. He or she has the option of paying the hospital's or CAH's charges for the blood or packed red cells or arranging for it to be replaced.

(2) *Exception.* The beneficiary is not responsible for the first 3 units of whole blood or packed red cells if the provider obtained that blood or red cells at no charge other than a processing or service charge. In that case,

the blood or red cells is deemed to have been replaced.

(c) *Provider's right to charge for the first 3 units of whole blood or packed red cells*—(1) *Basic rule*. Except as specified in paragraph (c)(2) of this section, a provider may charge a beneficiary its customary charge for any of the first 3 units of whole blood or packed red cells.

(2) *Exception*. A provider may not charge the beneficiary for the first 3 units of whole blood or packed red cells in any of the following circumstances:

(i) The blood or packed red cells has been replaced.

(ii) The provider (or its blood supplier) receives, from an individual or a blood bank, a replacement offer that meets the criteria specified in paragraph (d) of this section. The provider is precluded from charging even if it or its blood supplier rejects the replacement offer.

(iii) The provider obtained the blood or packed red cells at no charge other than a processing or service charge and it is therefore deemed to have been replaced.

(d) *Criteria for replacement of blood*. A blood replacement offer made by a beneficiary, or an individual or a blood bank on behalf of a beneficiary, discharges the beneficiary's obligation to pay for deductible blood or packed red cells if the replacement blood meets the applicable criteria specified in Food and Drug Administration regulations under 21 CFR part 640, i.e.—

(1) The replacement blood would not endanger the health of a recipient; and

(2) The prospective donor's health would not be endangered by making a blood donation.

[48 FR 12541, Mar. 25, 1983, as amended at 56 FR 8840, Mar. 1, 1991; 57 FR 36014, Aug. 12, 1992; 58 FR 30666, 30667, May 26, 1993]

§ 409.89 Exemption of kidney donors from deductible and coinsurance requirements.

The deductible and coinsurance requirements set forth in this subpart do not apply to any services furnished to an individual in connection with the donation of a kidney for transplant surgery.

Subpart H—Payment of Hospital Insurance Benefits

SOURCE: 53 FR 6633, Mar. 2, 1988, unless otherwise noted.

§ 409.100 To whom payment is made.

(a) *Basic rule*. Except as provided in paragraph (b) of this section—

(1) Medicare pays hospital insurance benefits only to a participating provider.

(2) For home health services (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA, payment is made to the HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

(b) *Exceptions*. Medicare may pay hospital insurance benefits as follows:

(1) For emergency services furnished by a nonparticipating hospital, to the hospital or to the beneficiary, under the conditions prescribed in subpart G of part 424 of this chapter.

(2) For services furnished by a Canadian or Mexican hospital, to the hospital or to the beneficiary, under the conditions prescribed in subpart H of part 424 of this chapter.

[53 FR 6633, Mar. 2, 1988, as amended at 65 FR 41211, July 3, 2000]

§ 409.102 Amounts of payment.

(a) The amounts Medicare pays for hospital insurance benefits are generally determined in accordance with part 412 or part 413 of this chapter.

(b) Except as provided in §§ 409.61(d) and 409.89, hospital insurance benefits are subject to the deductible and coinsurance requirements set forth in subpart G of this part.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 51 FR 41339, Nov. 14, 1986, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 410 appear at 62 FR 46037, Aug. 29, 1997.

Subpart A—General Provisions

§410.1 Basis and scope.

(a) *Statutory basis.* This part is based on the indicated provisions of the following sections of the Act:

(1) Section 1832—Scope of benefits furnished under the Medicare Part B supplementary medical insurance (SMI) program.

(2) Section 1833 through 1835 and 1862—Amounts of payment for SMI services, the conditions for payment, and the exclusions from coverage.

(3) Section 1861(qq)—Definition of the kinds of services that may be covered.

(4) Section 1865(b)—Permission for CMS to approve and recognize a national accreditation organization for the purpose of deeming entities accredited by the organization to meet program requirements.

(5) Section 1881—Medicare coverage for end-stage renal disease beneficiaries.

(6) Section 1842(o)—Payment for drugs and biologicals not paid on a cost or prospective payment basis.

(b) *Scope of part.* This part sets forth the benefits available under Medicare Part B, the conditions for payment and the limitations on services, the percentage of incurred expenses that Medicare Part B pays, and the deductible and copayment amounts for which the beneficiary is responsible. (Exclusions applicable to these services are set forth in subpart C of part 405 of this chapter. General conditions for Medicare payment are set forth in part 424 of this chapter.)

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 55 FR 53521, Dec. 31, 1990; 59 FR 63462, Dec. 8, 1994; 63 FR 58905, Nov. 2, 1998; 65 FR 83148, Dec. 29, 2000; 69 FR 66420, Nov. 15, 2004]

§410.2 Definitions.

As used in this part—

Community mental health center (CMHC) means an entity that—

(1) Provides outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and residents of its mental health service area who have been discharged from inpatient treatment at a mental health facility;

(2) Provides 24-hour-a-day emergency care services;

(3) Provides day treatment or other partial hospitalization services, or psychosocial rehabilitation services;

(4) Provides screening for patients being considered for admission to State mental health facilities to determine the appropriateness of this admission; and

(5) Meets applicable licensing or certification requirements for CMHCs in the State in which it is located.

Encounter means a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.

Nominal charge provider means a provider that furnishes services free of charge or at a nominal charge, and is either a public provider or another provider that (1) demonstrates to CMS's satisfaction that a significant portion of its patients are low-income; and (2) requests that payment for its services be determined accordingly.

Outpatient means a person who has not been admitted as an inpatient but who is registered on the hospital or CAH records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH.

Partial hospitalization services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care and furnishes the services described in § 410.43.

Participating refers to a hospital, CAH, SNF, HHA, CORF, or hospice that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has a provider agreement to participate in Medicare but only for purposes of providing outpatient physical therapy, occupational therapy, or speech pathology services; or a CMHC that has in effect a similar agreement but only for purposes of providing partial hospitalization services, and *nonparticipating* refers to a hospital, CAH, SNF, HHA, CORF, hospice, clinic, rehabilitation agency, public health agency, or CMHC that does not have in effect a provider agreement to participate in Medicare.

[59 FR 6577, Feb. 11, 1994, as amended at 62 FR 46025, Aug. 29, 1997; 65 FR 18536, Apr. 7, 2000]

§ 410.3 Scope of benefits.

(a) *Covered services.* The SMI program helps pay for the following:

(1) Medical and other health services such as physicians' services, outpatient services furnished by a hospital or a CAH, diagnostic tests, outpatient physical therapy and speech pathology services, rural health clinic services, Federally qualified health center services, IHS, Indian tribe, or tribal organization facility services, and outpatient renal dialysis services.

(2) Services furnished by ambulatory surgical centers (ASCs), home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), and partial hospitalization services provided by community mental health centers (CMHCs).

(3) Other medicial services, equipment, and supplies that are not covered under Medicare Part A hospital insurance.

(b) *Limitations on amount of payment.* (1) Medicare Part B does not pay the full reasonable costs or charges for all covered services. The beneficiary is responsible for an annual deductible and a blood deductible and, after the annual deductible has been satisfied, for coinsurance amounts specified for most of the services.

(2) Specific rules on payment are set forth in subpart E of this part.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 24981, June 12, 1992; 58 FR 30668, May 26, 1993; 59 FR 6577, Feb. 11, 1994; 66 FR 55328, Nov. 1, 2001]

§ 410.5 Other applicable rules.

The following other rules of this chapter set forth additional policies and procedures applicable to four of the kinds of services covered under the SMI program:

(a) Part 405, subpart U: End-Stage Renal Disease services.

(b) Part 405, Subpart X: Rural Health Clinic and Federally Qualified Health Center services.

(c) Part 416: Ambulatory Surgical Center services.

(d) Part 493: Laboratory Services.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 7134, Feb. 28, 1992; 57 FR 24981, June 12, 1992]

Subpart B—Medical and Other Health Services

§ 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, ''medical and other health services'' includes the following services:

(a) Physicians' services.

(b) Services and supplies furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

(c) Services and supplies, including partial hospitalization services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or a CAH if the services are services that the hospital or CAH ordinarily furnishes to its outpatients for diagnostic study.

(e) Diagnostic laboratory and X-ray tests (including diagnostic mammography that meets the conditions for coverage specified in § 410.34(b) of this subpart) and other diagnostic tests.

(f) X-ray therapy and other radiation therapy services.

(g) Medical supplies, appliances, and devices.

(h) Durable medical equipment.

(i) Ambulance services.

(j) Rural health clinic services.

(k) Home dialysis supplies and equipment; on or after July 1, 1991, epoetin (EPO) for home dialysis patients, and, on or after January 1, 1994, for dialysis patients, competent to use the drug; self-care home dialysis support services; and institutional dialysis services and supplies.

(l) Pneumococcal vaccinations.

(m) Outpatient physical therapy and speech pathology services.

(n) Cardiac pacemakers and pacemaker leads.

(o) Additional services furnished to enrollees of HMOs or CMPs, as described in § 410.58.

(p) Hepatitis B vaccine.

(q) Blood clotting factors for hemophilia patients competent to use these factors without medical or other supervision.

(r) Screening mammography services.

(s) Federally qualified health center services.

(t) Services of a certified registered nurse anesthetist or an anesthesiologist's assistant.

(u) Prescription drugs used in immunosuppressive therapy.

(v) Clinical psychologist services and services and supplies furnished as an incident to the services of a clinical psychologist, as provided in § 410.71.

(w) Clinical social worker services, as provided in § 410.73.

(x) Services of physicians and other practitioners furnished in or at the direction of an IHS or Indian tribal hospital or clinic.

(y) Intravenous immune globulin administered in the home for the treatment of primary immune deficiency diseases.

[51 FR 41339, Nov. 14, 1986, as amended at 52 FR 27765, July 23, 1987; 55 FR 22790, June 4, 1990; 55 FR 53522, Dec. 31, 1990; 56 FR 8841, Mar. 1, 1991; 56 FR 43709, Sept. 4, 1991; 57 FR 24981, June 12, 1992; 57 FR 33896, July 31, 1992; 58 FR 30668, May 26, 1993; 59 FR 26959, May 25, 1994; 59 FR 49833, Sept. 30, 1994; 60 FR 8955, Feb. 16, 1995; 63 FR 20128, Apr. 23, 1998; 66 FR 55328, Nov. 1, 2001; 69 FR 66420, Nov. 15, 2004]

§ 410.12 Medical and other health services: Basic conditions and limitations.

(a) *Basic conditions.* The medical and other health services specified in § 410.10 are covered by Medicare Part B only if they are not excluded under subpart A of part 411 of this chapter, and if they meet the following conditions:

(1) *When the services must be furnished.* The services must be furnished while the individual is in a period of entitlement. (The rules on entitlement are set forth in part 406 of this chapter.)

(2) *By whom the services must be furnished.* The services must be furnished by a facility or other entity as specified in §§ 410.14 through 410.69.

(3) *Physician certification and recertification requirements.* If the services are subject to physician certification requirements, they must be certified as being medically necessary, and as meeting other applicable requirements, in accordance with subpart B of part 424 of this chapter.

(b) *Limitations on payment.* Payment for medical and other health services is subject to limitations on the amounts of payment as specified in §§ 410.152 and 410.155 and to the annual and blood deductibles as set forth in §§ 410.160 and 410.161.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 33896, July 31, 1992]

§ 410.14 Special requirements for services furnished outside the United States.

Medicare part B pays for physicians' services and ambulance services furnished outside the United States if the services meet the applicable conditions of § 410.12 and are furnished in connection with covered inpatient hospital services that meet the specific requirements and conditions set forth in subpart H of part 424 of this chapter.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.16 Initial preventive physical examination: Conditions for and limitations on coverage.

(a) *Definitions.* As used in this section, the following definitions apply:

Eligible beneficiary means an individual who receives his or her initial preventive physical examination within 6 months after the effective date of his or her first Medicare Part B coverage period, but only if that first Part B coverage period begins on or after January 1, 2005.

Initial preventive physical examination means all of the following services furnished to an eligible beneficiary by a physician or other qualified nonphysician practitioner with the goal of health promotion and disease detection:

(1) Review of the beneficiary's medical and social history with attention to modifiable risk factors for disease, as those terms are defined in this section.

(2) Review of the beneficiary's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests designed for this purpose and recognized by national professional medical organizations.

(3) Review of the beneficiary's functional ability, and level of safety as those terms are defined in this section, as described in paragraph (4) of this definition, based on the use of appropriate screening questions or a screening questionnaire, which the physician or other qualified nonphysician practitioner may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

(4) An examination to include measurement of the beneficiary's height, weight, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary's medical and social history, and current clinical standards.

(5) Performance and interpretation of an electrocardiogram.

(6) Education, counseling, and referral, as deemed appropriate by the physician or qualified nonphysician practitioner, based on the results of the review and evaluation services described in this section.

(7) Education, counseling, and referral, including a brief written plan such as a checklist provided to the beneficiary for obtaining the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in section 1861(s)(10), section 1861(jj), section 1861(nn), section 1861(oo), section 1861(pp), section 1861(qq)(1), section 1861(rr), section 1861(uu), section 1861(vv), section 1861(xx)(1), and section 1861(yy) of the Act.

Medical history is defined to include, at a minimum, the following:

(1) Past medical and surgical history, including experiences with illnesses,

hospital stays, operations, allergies, injuries, and treatments.

(2) Current medications and supplements, including calcium and vitamins.

(3) Family history, including a review of medical events in the beneficiary's family, including diseases that may be hereditary or place the individual at risk.

A *physician* for purposes of this section means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

A qualified nonphysician practitioner for purposes of this section means a physician assistant, nurse practitioner, or clinical nurse specialist (as authorized under section 1861(s)(2)((K)(i) and section 1861(s)(2)((K)(ii) of the Act and defined in section 1861(aa)(5) of the Act, or in § 410.74, § 410.75, and § 410.76).

Review of the beneficiary's functional ability and level of safety must include, at a minimum, a review of the following areas:

(1) Hearing impairment.

(2) Activities of daily living.

(3) Falls risk.

(4) Home safety

Social history is defined to include, at a minimum, the following:

(1) History of alcohol, tobacco, and illicit drug use.

(2) Diet.

(3) Physical activities.

(b) *Condition for coverage of an initial preventive physical examination.* Medicare Part B pays for an initial preventive physical examination provided to an eligible beneficiary, as described in this section, if it is furnished by a physician or other qualified nonphysician practitioner, as defined in this section.

(c) *Limitations on coverage of initial preventive physical examinations.* Payment may not be made for an initial preventive physical preventive examination that is performed for an individual who is not an eligible beneficiary as described in this section.

[69 FR 66420, Nov. 15, 2004]

§ 410.17 Cardiovascular disease screening tests.

(a) *Definition.* For purposes of this subpart, the following definition apply:

Cardiovascular screening blood test means:

(1) A lipid panel consisting of a total cholesterol, HDL cholesterol, and triglyceride. The test is performed after a 12-hour fasting period.

(2) Other blood tests, previously recommended by the U.S. Preventive Services Task Force (USPSTF), as determined by the Secretary through a national coverage determination process.

(3) Other non-invasive tests, for indications that have a blood test recommended by the USPSTF, as determined by the Secretary through a national coverage determination process.

(b) *General conditions of coverage.* Medicare Part B covers cardiovascular disease screening tests when ordered by the physician who is treating the beneficiary (*see* § 410.32(a)) for the purpose of early detection of cardiovascular disease in individuals without apparent signs or symptoms of cardiovascular disease.

(c) *Limitation on coverage of cardiovascular screening tests.* Payment may be made for cardiovascular screening tests performed for an asymptomatic individual only if the individual has not had the screening tests paid for by Medicare during the preceding 59 months following the month in which the last cardiovascular screening tests were performed.

[69 FR 66421, Nov. 15, 2004]

§ 410.18 Diabetes screening tests.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2-hour post-glucose challenge greater than or equal to 200 mg/dL on two different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

Pre-diabetes means a condition of abnormal glucose metabolism diagnosed using the following criteria: a fasting glucose level of 100—125 mg/dL, or a 2-hour post-glucose challenge of 140—199 mg/dL. The term pre-diabetes includes the following conditions:

(1) Impaired fasting glucose.

(2) Impaired glucose tolerance.

(b) *General conditions of coverage.* Medicare Part B covers diabetes screening tests after a referral from a physician or qualified nonphysician practitioner to an individual at risk for diabetes for the purpose of early detection of diabetes.

(c) *Types of tests covered.* The following tests are covered if all other conditions of this subpart are met:

(1) Fasting blood glucose test.

(2) Post-glucose challenges including, but not limited to, an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for non-pregnant adults, a 2-hour post glucose challenge test alone.

(3) Other tests as determined by the Secretary through a national coverage determination.

(d) *Amount of testing covered.* Medicare covers the following for individuals:

(1) Diagnosed with pre-diabetes, two screening tests per calendar year.

(2) Previously tested who were not diagnosed with pre-diabetes, or who were never tested before, one screening test per year.

(e) *Eligible risk factors.* Individuals with the following risk factors are eligible to receive the benefit:

(1) Hypertension.

(2) Dyslipidemia.

(3) Obesity, defined as a body mass index greater than or equal to 30 kg/m^2.

(4) Prior identification of impaired fasting glucose or glucose intolerance.

(5) Any two of the following characteristics:

(i) Overweight, defined as body mass index greater than 25, but less than 30 kg/m^2.

(ii) A family history of diabetes.

(iii) 65 years of age or older.

(iv) A history of gestational diabetes mellitus or delivery of a baby weighing more than 9 pounds.

[69 FR 66421, Nov. 15, 2004]

§ 410.20 Physicians' services.

(a) *Included services.* Medicare Part B pays for physicians' services, including diagnosis, therapy, surgery, consultations, and home, office, and institutional calls.

(b) *By whom services must be furnished.* Medicare Part B pays for the services specified in paragraph (a) of this section if they are furnished by one of the following professionals who is legally authorized to practice by the State in which he or she performs the functions or actions, and who is acting within the scope of his or her license.

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized in section 1101(a)(7) of the Act.

(2) A doctor of dental surgery or dental medicine.

(3) A doctor of podiatric medicine.

(4) A doctor of optometry.

(5) A chiropractor who meets the qualifications specified in § 410.22

(c) *Limitations on services.* The Services specified in paragraph (a) of this section may be covered under Medicare Part B if they are furnished within the limitations specified in §§ 410.22 through 410.25.

§ 410.21 Limitations on services of a chiropractor.

(a) *Qualifications for chiropractors.* (1) A chiropractor licensed or authorized to practice before July 1, 1974, and an individual who began studies in a chiropractic college before that date, must have—

(i) Had preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

(ii) Graduated from a college of chiropractic approved by the State's chiropractic examiners after completing a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous attendance and covering adequate courses of study in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing and adjusting; and

(iii) Passed an examination prescribed by the State's chiropractic examiners covering the subjects specified in paragraph (a)(1)(ii) of this section.

(2) A chiropractor first licensed or authorized to practice after June 30, 1974, and an individual who begins

studies in a chiropractic college after that date, must have—

(i) Had preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

(ii) Satisfactorily completed 2 years of pre-chiropractic study at the college level;

(iii) Satisfactorily completed a 4-year course of 8 months each year offered by a college or school of chiropractic approved by the State's chiropractic examiners and including at least 4,000 hours in courses in anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, principles and practice of chiropractic, and clinical instruction in vertebral palpation, nerve tracing and adjusting, plus courses in the use and effect of X-ray and chiropractic analysis;

(iv) Passed an examination prescribed by the State's chiropractic examiners covering the subjects specified in paragraph (a)(2)(iii) of this section; and

(v) Attained 21 years of age.

(b) *Limitations on services.* (1) Medicare Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation if the subluxation has resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment.

(2) Medicare Part B does not pay for X-rays or other diagnostic or therapeutic services furnished or ordered by a chiropractor.

[51 FR 41339, Nov. 14, 1986, as amended at 64 FR 59439, Nov. 2, 1999. Redesignated at 66 FR 55328, Nov. 1, 2001]

§ 410.22 Limitations on services of an optometrist.

Medicare Part B pays for the services of a doctor of optometry, which he or she is legally authorized to perform in the State in which he or she performs them, if the services are among those described in section 1861(s) of the Act and § 410.10 of this part.

[64 FR 59439, Nov. 2, 1999. Redesignated at 66 FR 55328, Nov. 1, 2001]

§ 410.23 Screening for glaucoma: Conditions for and limitations on coverage.

(a) *Definitions*: As used in this section, the following definitions apply:

(1) *Direct supervision in the office setting* means the optometrist or the ophthalmologist must be present in the office suite and be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean the physician must be present in the room when the procedure is performed.

(2) *Eligible beneficiary* means individuals in the following high risk categories:

(i) Individual with diabetes mellitus;

(ii) Individual with a family history of glaucoma; or

(iii) African-Americans age 50 and over.

(3) *Screening for glaucoma* means the following procedures furnished to an individual for the early detection of glaucoma:

(i) A dilated eye examination with an intraocular pressure measurement.

(ii) A direct ophthalmoscopy examination, or a slit-lamp biomicroscopic examination.

(b) *Condition for coverage of screening for glaucoma.*

Medicare Part B pays for glaucoma screening examinations provided to eligible beneficiaries as described in paragraph (a)(2) of this section if they are furnished by or under the direct supervision in the office setting of an optometrist or ophthalmologist who is legally authorized to perform these services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished, as would otherwise be covered if furnished by a physician or incident to a physician's professional service.

(c) *Limitations on coverage of glaucoma screening examinations.*

(1) Payment may not be made for a glaucoma screening examination that is performed for an individual who is not an eligible beneficiary as described in paragraph (a)(2) of this section.

(2) Payment may be made for a glaucoma screening examination that is performed on an individual who is an eligible beneficiary as described in

paragraph (a)(2) of this section, after at least 11 months have passed following the month in which the last glaucoma screening examination was performed.

[66 FR 55328, Nov. 1, 2001]

§ 410.24 Limitations on services of a doctor of dental surgery or dental medicine.

Medicare Part B pays for services furnished by a doctor of dental surgery or dental medicine within the scope of his or her license, if the services would be covered as physicians' services when performed by a doctor of medicine or osteopathy.[1]

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8852, Mar. 1, 1991]

§ 410.25 Limitations on services of a podiatrist.

Medicare Part B pays for the services of a doctor of podiatric medicine, acting within the scope of his or her license, if the services would be covered as physicians' services when performed by a doctor of medicine or osteopathy.

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Auxiliary personnel* means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner).

(2) *Direct supervision* means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii).

(3) *Independent contractor* means an individual (or an entity that has hired such an individual) who performs part-time or full-time work for which the individual (or the entity that has hired such an individual) receives an IRS–1099 form.

(4) *Leased employment* means an employment relationship that is recognized by applicable State law and that is established by two employers by a contract such that one employer hires the services of an employee of the other employer.

(5) *Noninstitutional setting* means all settings other than a hospital or skilled nursing facility.

(6) *Practitioner* means a non-physician practitioner who is authorized by the Act to receive payment for services incident to his or her own services.

(7) *Services and supplies* means any services or supplies (including drugs or biologicals that are not usually self-administered) that are included in section 1861(s)(2)(A) of the Act and are not specifically listed in the Act as a separate benefit included in the Medicare program.

(b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).

(1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

(2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

(3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).

(4) Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).

(5) Services and supplies must be furnished under the direct supervision of the physician (or other practitioner). The physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

(6) Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.

[1] For services furnished before July 1, 1981, Medicare Part B paid only for the following services of a doctor of dental surgery or dental medicine;

Surgery on the jaw or any adjoining structure; and

Reduction of a fracture of the jaw or other facial bone.

(7) A physician (or other practitioner) may be an employee or an independent contractor.

(c) *Limitations.* (1) Drugs and biologicals are also subject to the limitations specified in § 410.29.

(2) Physical therapy, occupational therapy and speech-language pathology services provided incident to a physician's professional services are subject to the provisions established in § 410.59(a)(3)(iii), § 410.60(a)(3)(iii), and § 410.62(a)(3)(ii).

[51 FR 41339, Nov. 14, 1986, as amended at 66 FR 55328, Nov. 1, 2001; 67 FR 20684, Apr. 26, 2002; 69 FR 66421, Nov. 15, 2004]

§ 410.27 Outpatient hospital services and supplies incident to a physician service: Conditions.

(a) Medicare Part B pays for hospital services and supplies furnished incident to a physician service to outpatients, including drugs and biologicals that cannot be self-administered, if—

(1) They are furnished—

(i) By or under arrangements made by a participating hospital, except in the case of an SNF resident as provided in § 411.15(p) of this chapter;

(ii) As an integral though incidental part of a physician's services; and

(iii) In the hospital or at a location (other than an RHC or an FQHC) that CMS designates as a department of a provider under § 413.65 of this chapter; and

(2) In the case of partial hospitalization services, also meet the conditions of paragraph (d) of this section.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.168.

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in § 410.168.

(d) Medicare Part B pays for partial hospitalization services if they are—

(1) Prescribed by a physician who certifies and recertifies the need for the services in accordance with subpart B of part 424 of this chapter; and

(2) Furnished under a plan of treatment as required under subpart B of part 424 of this chapter.

(e) Services furnished by an entity other than the hospital are subject to the limitations specified in § 410.42(a).

(f) Services furnished at a location (other than an RHC or an FQHC) that CMS designates as a department of a provider under § 413.65 of this chapter must be under the direct supervision of a physician. ''Direct supervision'' means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

[56 FR 8841, Mar. 1, 1991, as amended at 63 FR 26307, May 12, 1998; 65 FR 18536, Apr. 7, 2000]

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

(a) Medicare Part B pays for hospital or CAH diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

(1) They are furnished by or under arrangements made by a participating hospital or participating CAH, except in the case of an SNF resident as provided in § 411.15(p) of this chapter.

(2) They are ordinarily furnished by, or under arrangements made by, the hospital or CAH to its outpatients for the purpose of diagnostic study.

(3) They would be covered as inpatient hospital services if furnished to an inpatient.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29(b) and (c).

(c) Diagnostic services furnished by an entity other than the hospital or CAH are subject to the limitations specified in § 410.42(a).

(d) Rules on emergency services furnished to outpatients by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

(e) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished at a facility (other than an RHC or an FQHC) that CMS designates as having provider-based status only when the diagnostic services are furnished under the appropriate level of physician supervision

specified by CMS in accordance with the definitions in § 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). Under general supervision at a facility accorded provider-based status, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility.

(f) The rules for clinical diagnostic laboratory tests set forth in §§ 410.32(a) and (d)(2) through (d)(4) of this subpart are applicable to those tests when furnished in hospitals and CAHs.

[51 FR 41339, Nov. 14, 1986, as amended at 58 FR 30668, May 26, 1993; 63 FR 26307, May 12, 1998; 65 FR 18536, Apr. 7, 2000; 66 FR 58809, Nov. 23, 2001]

§ 410.29 Limitations on drugs and biologicals.

Medicare part B does not pay for the following:

(a) Except as provided in § 410.28(a) for outpatient diagnostic services and § 410.63(b) for blood clotting factors, and except for EPO, any drug or biological that can be self-administered.

(b) Any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program, that there is a compelling justification of the drug product's medical need. (21 CFR 310.6 contains an explanation of the efficacy review program.)

(c) Any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (b) of this section.

[51 FR 41339, Nov. 14, 1986, as amended at 55 FR 22790, June 4, 1990; 56 FR 43709, Sept. 4, 1991]

§ 410.30 Prescription drugs used in immunosuppressive therapy.

(a) *Scope*. Payment may be made for prescription drugs used in immunosuppressive therapy that have been approved for marketing by the FDA and that meet one of the following conditions:

(1) The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.

(2) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(3) Have been determined by a carrier (in accordance with part 421, subpart C of this chapter), in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. (In making these determinations, the carriers may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

(b) *Period of eligibility*. Coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who receives an organ or tissue transplant for which Medicare payment is made, for the following periods:

(1) For drugs furnished before 1995, for a period of up to 1 year beginning with the date of discharge from the hospital during which the covered transplant was performed.

(2) For drugs furnished during 1995, within 18 months after the date of discharge from the hospital during which the covered transplant was performed.

(3) For drugs furnished during 1996, within 24 months after the date of discharge from the hospital during which the covered transplant was performed.

(4) For drugs furnished during 1997, within 30 months after the date of discharge from the hospital during which the covered transplant was performed.

(5) For drugs furnished after 1997, within 36 months after the date of discharge from the hospital during which the covered transplant was performed.

(c) *Coverage*. Drugs are covered under this provision irrespective of whether they can be self-administered.

[60 FR 8955, Feb. 16, 1995. Redesignated at 63 FR 34327, June 24, 1998]

§ 410.31 Bone mass measurement: Conditions for coverage and frequency standards.

(a) *Definition*. As used in this section unless specified otherwise, the following definition applies:

Bone mass measurement means a radiologic, radioisotopic, or other procedure that meets the following conditions:

(1) Is performed for the purpose of identifying bone mass, detecting bone loss, or determining bone quality.

(2) Is performed with either a bone densitometer (other than dual-photon absorptiometry) or with a bone sonometer system that has been cleared for marketing for this use by the FDA under 21 CFR part 807, or approved for marketing by the FDA for this use under 21 CFR part 814.

(3) Includes a physician's interpretation of the results of the procedure.

(b) *Conditions for coverage*. Medicare covers a medically necessary bone mass measurement if the following conditions are met:

(1) Following an evaluation of the beneficiary's need for the measurement, including a determination as to the medically appropriate procedure to be used for the beneficiary, it is ordered by the physician or a qualified nonphysician practitioner (as these terms are defined in § 410.32(a)) treating the beneficiary.

(2) It is performed under the appropriate level of supervision of a physician (as set forth in § 410.32(b)).

(3) It is reasonable and necessary for diagnosing, treating, or monitoring the condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(c) *Standards on frequency of coverage*—(1) *General rule*. Except as allowed under paragraph (c)(2) of this section, Medicare may cover a bone mass measurement for a beneficiary if at least 23 months have passed since the month the last bone mass measurement was performed.

(2) *Exception*. If medically necessary, Medicare may cover a bone mass measurement for a beneficiary more frequently than allowed under paragraph (c)(1) of this section. Examples of situations where more frequent bone mass measurement procedures may be medically necessary include, but are not limited to, the following medical circumstances:

(i) Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months.

(ii) Allowing for a confirmatory baseline bone mass measurement (either central or peripheral) to permit monitoring of beneficiaries in the future if the initial test was performed with a technique that is different from the proposed monitoring method.

(d) *Beneficiaries who may be covered*. The following categories of beneficiaries may receive Medicare coverage for a medically necessary bone mass measurement:

(1) A woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

(2) An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

(3) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to 7.5 mg of prednisone, or greater, per day for more than 3 months.

(4) An individual with primary hyperparathyroidism.

(5) An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

(e) *Denial as not reasonable and necessary*. If CMS determines that a bone

mass measurement does not meet the conditions for coverage in paragraphs (b) or (d) of this section, or the standards on frequency of coverage in paragraph (c) of this section, it is excluded from Medicare coverage as not ''reasonable'' and ''necessary'' under section 1862(a)(1)(A) of the Act and § 411.15(k) of this chapter.

[63 FR 34327, June 24, 1998]

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Ordering diagnostic tests.* All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(1) *Chiropractic exception.* A physician may order an x-ray to be used by a chiropractor to demonstrate the subluxation of the spine that is the basis for a beneficiary to receive manual manipulation treatments even though the physician does not treat the beneficiary.

(2) *Mammography exception.* A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in § 410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

(3) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

(b) *Diagnostic x-ray and other diagnostic tests*—(1) *Basic rule.* Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) *Exceptions.* The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.

(iii) Diagnostic psychological testing services when—

(A) Personally furnished by a clinical psychologist or an independently practicing psychologist as defined in program instructions; or

(B) Furnished under the general supervision of a physician or a clinical psychologist.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(v) Diagnostic tests performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.

(vi) Pathology and laboratory procedures listed in the 80000 series of the Current Procedural Terminology published by the American Medical Association.

(3) *Levels of supervision.* Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of

physician supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraphs (b)(3)(ii) or (b)(3)(iii) of this section, respectively. (However, diagnostic tests performed by a physician assistant (PA) that the PA is legally authorized to perform under State law require only a general level of physician supervision.) When direct or personal supervision is required, physician supervision at the specified level is required throughout the performance of the test.

(i) *General supervision* means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

(ii) *Direct supervision* in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

(iii) *Personal supervision* means a physician must be in attendance in the room during the performance of the procedure.

(c) *Portable x-ray services.* Portable x-ray services furnished in a place of residence used as the patient's home are covered if the following conditions are met:

(1) These services are furnished under the general supervision of a physician, as defined in paragraph (b)(3)(i) of this section.

(2) The supplier of these services meets the requirements set forth in part 486, subpart C of this chapter, concerning conditions for coverage for portable x-ray services.

(3) The procedures are limited to—

(i) Skeletal films involving the extremities, pelvis, vertebral column, or skull;

(ii) Chest or abdominal films that do not involve the use of contrast media; and

(iii) Diagnostic mammograms if the approved portable x-ray supplier, as defined in subpart C of part 486 of this chapter, meets the certification requirements of section 354 of the Public Health Service Act, as implemented by 21 CFR part 900, subpart B.

(d) *Diagnostic laboratory tests.* (1) *Who may furnish services.* Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following:

(i) A participating hospital or participating RPCH.

(ii) A nonparticipating hospital that meets the requirements for emergency outpatient services specified in subpart G of part 424 of this chapter and the laboratory requirements specified in part 493 of this chapter.

(iii) The office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, podiatric medicine, dental surgery, or dental medicine.

(iv) An RHC.

(v) A laboratory, if it meets the applicable requirements for laboratories of part 493 of this chapter, including the laboratory of a nonparticipating hospital that does not meet the requirements for emergency outpatient services in subpart G of part 424 of this chapter.

(vi) An FQHC.

(vii) An SNF to its resident under § 411.15(p) of this chapter, either directly (in accordance with § 483.75(k)(1)(i) of this chapter) or under an arrangement (as defined in § 409.3 of this chapter) with another entity described in this paragraph.

(2) *Documentation and recordkeeping requirements.*

(i) *Ordering the service.* The physician or (qualified nonphysican practitioner, as defined in paragraph (a)(3) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

(ii) *Submitting the claim.* The entity submitting the claim must maintain the following documentation:

(A) The documentation that it receives from the ordering physician or nonphysician practitioner.

(B) The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner.

(iii) *Requesting additional information.* The entity submitting the claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(3) *Claims review.* (i) *Documentation requirements.* Upon request by CMS, the entity submitting the claim must provide the following information:

(A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).

(B) Documentation showing accurate processing of the order and submission of the claim.

(C) Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

(ii) *Services that are not reasonable and necessary.* If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, CMS takes the following actions:

(A) Provides the ordering physician or nonphysician practitioner information sufficient to identify the claim being reviewed.

(B) Requests from the ordering physician or nonphysician practitioner those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.

(C) If the ordering physician or nonphysician practitioner does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.

(iii) *Medical necessity.* The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(4) *Automatic denial and manual review.* (i) *General rule.* Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

(ii) *Exceptions.* CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by law.

(e) Diagnostic laboratory tests furnished in hospitals and CAHs. The provisions of paragraphs (a) and (d)(2) through (d)(4), inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

[62 FR 59098, Oct. 31, 1997, as amended at 63 FR 26308, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 63 FR 58906, Nov. 2, 1998; 64 FR 59440, Nov. 2, 1999; 66 FR 58809, Nov. 23, 2001; 69 FR 66421, Nov. 15, 2004]

§ 410.33 Independent diagnostic testing facility.

(a) *General rule.* (1) Effective for diagnostic procedures performed on or after March 15, 1999, carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, an approved supplier of portable x-ray services, a nurse practitioner, or a clinical nurse specialist when he or she performs a test he or she is authorized by the State to perform, or an independent diagnostic testing facility (IDTF). An IDTF may be a fixed location, a mobile entity, or

an individual nonphysician practitioner. It is independent of a physician's office or hospital; however, these rules apply when an IDTF furnishes diagnostic procedures in a physician's office.

(2) *Exceptions.* The following diagnostic tests that are payable under the physician fee schedule and furnished by a nonhospital testing entity are not required to be furnished in accordance with the criteria set forth in paragraphs (b) through (e) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.

(iii) Diagnostic psychological testing services personally furnished by a clinical psychologist or a qualified independent psychologist as defined in program instructions.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(b) *Supervising physician.* (1) An IDTF must have one or more supervising physicians who are responsible for the direct and ongoing oversight of the quality of the testing performed, the proper operation and calibration of the equipment used to perform tests, and the qualification of nonphysician personnel who use the equipment. This level of supervision is that required for general supervision set forth in §410.32(b)(3)(i).

(2) The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located. In the case of a procedure requiring the direct or personal supervision of a physician as set forth in §410.32(b)(3)(ii) or (b)(3)(iii), the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location. The IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished. In the case of procedures requiring direct supervision, the supervising physician may oversee concurrent procedures.

(c) *Nonphysician personnel.* Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

(d) *Ordering of tests.* All procedures performed by the IDTF must be specifically ordered in writing by the physician who is treating the beneficiary, that is, the physician who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. (Nonphysician practitioners may order tests as set forth in §410.32(a)(3).) The order must specify the diagnosis or other basis for the testing. The supervising physician for the IDTF may not order tests to be performed by the IDTF, unless the IDTF's supervising physician is in fact the beneficiary's treating physician. That is, the physician in question had a relationship with the beneficiary prior to the performance of the testing and is treating the beneficiary for a specific medical problem. The IDTF may not add any procedures based on internal protocols without a written order from the treating physician.

(e) *Multi-State entities.* An IDTF that operates across State boundaries must maintain documentation that its supervising physicians and technicians are licensed and certified in each of the States in which it is furnishing services.

(f) *Applicability of State law*. An IDTF must comply with the applicable laws of any State in which it operates.

[62 FR 59099, Oct. 31, 1997, as amended at 64 FR 59440, Nov. 2, 1999]

§ 410.34 Mammography services: Conditions for and limitations on coverage.

(a) *Definitions*. As used in this section, the following definitions apply:

(1) *Diagnostic mammography* means a radiologic procedure furnished to a man or woman with signs or symptoms of breast disease, or a personal history of breast cancer, or a personal history of biopsy-proven benign breast disease, and includes a physician's interpretation of the results of the procedure.

(2) *Screening mammography* means a radiologic procedure furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure.

(3) *Supplier of diagnostic mammography* means a facility that is certified and responsible for ensuring that all diagnostic mammography services furnished to Medicare beneficiaries meet the conditions for coverage of diagnostic mammography services as specified in paragraph (b) of this section.

(4) *Supplier of screening mammography* means a facility that is certified and responsible for ensuring that all screening mammography services furnished to Medicare beneficiaries meet the conditions and limitations for coverage of screening mammography services as specified in paragraphs (c) and (d) of this section.

(5) *Certificate* means the certificate described in 21 CFR 900.2(b) that may be issued to, or renewed for, a facility that meets the requirements for conducting an examination or procedure involving mammography.

(6) *Provisional certificate* means the provisional certificate described in 21 CFR 900.2(m) that may be issued to a facility to enable the facility to qualify to meet the requirements for conducting an examination or procedure involving mammography.

(7) The term *meets the certification requirements of section 354 of the Public Health Service (PHS) Act* means that in order to qualify for coverage of its services under the Medicare program, a supplier of diagnostic or screening mammography services must meet the following requirements:

(i) Must have a valid provisional certificate, or a valid certificate, that has been issued by FDA indicating that the supplier meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(ii) Has not been issued a written notification by FDA that states that the supplier must cease conducting mammography examinations because the supplier is not in compliance with certain critical certification requirements of section 354 of the PHS Act, implemented by 21 CFR part 900, subpart B.

(iii) Must not employ for provision of the professional component of mammography services a physician or physicians for whom the facility has received written notification by FDA that the physician (or physicians) is (or are) in violation of the certification requirements set forth in section 354 of the PHS Act, as implemented by 21 CFR 900.12(a)(1)(i).

(b) *Conditions for coverage of diagnostic mammography services*. Medicare Part B pays for diagnostic mammography services if they meet the following conditions:

(1) They are ordered by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(2) They are furnished by a supplier of diagnostic mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(c) *Conditions for coverage of screening mammography services*. Medicare Part B pays for screening mammography services if they are furnished by a supplier of screening mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(d) *Limitations on coverage of screening mammography services*. The following limitations apply to coverage of screening mammography services as described in paragraphs (c) and (d) of this section:

(1) The service must be, at a minimum a two-view exposure (that is, a cranio-caudal and a medial lateral oblique view) of each breast.

(2) Payment may not be made for screening mammography performed on a woman under age 35.

(3) Payment may be made for only 1 screening mammography performed on a woman over age 34, but under age 40.

(4) For an asymptomatic woman over 39 years of age, payment may be made for a screening mammography performed after at least 11 months have passed following the month in which the last screening mammography was performed.

[59 FR 49833, Sept. 30, 1994, as amended at 60 FR 14224, Mar. 16, 1995; 60 FR 63176, Dec. 8, 1995; 62 FR 59100, Oct. 31, 1997; 63 FR 4596, Jan. 30, 1998]

§ 410.35 X-ray therapy and other radiation therapy services: Scope.

Medicare Part B pays for X-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

[51 FR 41339, Nov. 14, 1986. Redesignated at 55 FR 53522, Dec. 31, 1990]

§ 410.36 Medical supplies, appliances, and devices: Scope.

(a) Medicare Part B pays for the following medical supplies, appliances and devices:

(1) Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations.

(2) Prosthetic devices, other than dental, that replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, including—

(i) Replacement of prosthetic devices; and

(ii) One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery during which an intraocular lens is inserted.

(3) Leg, arm, back, and neck braces and artificial legs, arms, and eyes, including replacements if required because of a change in the individual's physical condition.

(b) As a requirement for payment, CMS may determine through carrier instructions, or carriers may determine, that an item listed in paragraph (a) of this section requires a written physician order before delivery of the item.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 36014, Aug. 12, 1992; 57 FR 57688, Dec. 7, 1992]

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

(a) *Definitions*. As used in this section, the following definitions apply:

(1) *Colorectal cancer screening tests* means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:

(i) Screening fecal-occult blood tests.

(ii) Screening flexible sigmoidoscopies.

(iii) In the case of an individual at high risk for colorectal cancer, screening colonoscopies.

(iv) Screening barium enemas.

(v) Other tests or procedures established by a national coverage determination, and modifications to tests under this paragraph, with such frequency and payment limits as CMS determines appropriate, in consultation with appropriate organizations

(2) *Screening fecal-occult blood test* means—

(i) A guaiac-based test for peroxidase activity, testing two samples from each of three consecutive stools, or,

(ii) Other tests as determined by the Secretary through a national coverage determination.

(3) An *individual at high risk for colorectal cancer* means an individual with—

(i) A close relative (sibling, parent, or child) who has had colorectal cancer or an adenomatous polyp;

(ii) A family history of familial adenomatous polyposis;

(iii) A family history of hereditary nonpolyposis colorectal cancer;

(iv) A personal history of adenomatous polyps; or

(v) A personal history of colorectal cancer; or

(vi) Inflammatory bowel disease, including Crohn's Disease, and ulcerative colitis.

(4) *Screening barium enema* means—

(i) A screening double contrast barium enema of the entire colorectum (including a physician's interpretation of the results of the procedure); or

(ii) In the case of an individual whose attending physician decides that he or she cannot tolerate a screening double contrast barium enema, a screening single contrast barium enema of the entire colorectum (including a physician's interpretation of the results of the procedure).

(5) An *attending physician for purposes of this provision* is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible using the results of any examination performed in the overall management of the beneficiary's specific medical problem.

(b) *Condition for coverage of screening fecal-occult blood tests.* Medicare Part B pays for a screening fecal-occult blood test if it is ordered in writing by the beneficiary's attending physician.

(c) *Limitations on coverage of screening fecal-occult blood tests.* (1) Payment may not be made for a screening fecal-occult blood test performed for an individual under age 50.

(2) For an individual 50 years of age or over, payment may be made for a screening fecal-occult blood test performed after at least 11 months have passed following the month in which the last screening fecal-occult blood test was performed.

(d) *Condition for coverage of flexible sigmoidoscopy screening.* Medicare Part B pays for a flexible sigmoidoscopy screening service if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act), or by a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act and §§ 410.74, 410.75, and 410.76) who is authorized under State law to perform the examination.

(e) *Limitations on coverage of screening flexible sigmoidoscopies.* (1) Payment may not be made for a screening flexible sigmoidoscopy performed for an individual under age 50.

(2) For an individual 50 years of age or over, except as described in paragraph (e)(3) of this section, payment may be made for screening flexible sigmoidoscopy after at least 47 months have passed following the month in which the last screening flexible sigmoidoscopy or, as provided in paragraphs (h) and (i) of this section, the last screening barium enema was performed.

(3) In the case of an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section but who has had a screening colonoscopy performed, payment may be made for a screening flexible sigmoidosocopy only after at least 119 months have passed following the month in which the last screening colonoscopy was performed.

(f) *Condition for coverage of screening colonoscopies.* Medicare Part B pays for a screening colonoscopy if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(g) *Limitations on coverage of screening colonoscopies.* (1) Effective for services furnished on or after January 1, 1998 through June 30, 2001, payment may not be made for a screening colonoscopy for an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section.

(2) Effective for services furnished on or after July 1, 2001, except as described in paragraph (g)(4) of this section, payment may be made for a screening colonoscopy performed for an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section, after at least 119 months have passed following the month in which the last screening colonoscopy was performed.

(3) Payment may be made for a screening colonoscopy performed for an individual who is at high risk for colorectal cancer as described in paragraph (a)(3) of this section, after at least 23 months have passed following the month in which the last screening colonoscopy was performed, or, as provided in paragraphs (h) and (i) of this

section, the last screening barium enema was performed.

(4) In the case of an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section but who has had a screening flexible sigmoidoscopy performed, payment may be made for a screening colonoscopy only after at least 47 months have passed following the month in which the last screening flexible sigmoidoscopy was performed.

(h) *Conditions for coverage of screening barium enemas.* Medicare Part B pays for a screening barium enema if it is ordered in writing by the beneficiary's attending physician.

(i) *Limitations on coverage of screening barium enemas.* (1) In the case of an individual age 50 or over who is not at high risk of colorectal cancer, payment may be made for a screening barium enema examination performed after at least 47 months have passed following the month in which the last screening barium enema or screening flexible sigmoidoscopy was performed.

(2) In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination performed after at least 23 months have passed following the month in which the last screening barium enema or the last screening colonoscopy was performed.

[62 FR 59100, Oct. 31, 1997, as amended at 66 FR 55329, Nov. 1, 2001; 67 FR 80040, Dec. 31, 2002]

§ 410.38 Durable medical equipment: Scope and conditions.

(a) Medicare Part B pays for the rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) An institution that is used as a home may not be a hospital or a CAH or a SNF as defined in sections 1861(e)(1), 1861(mm)(1) and 1819(a)(1) of the Act, respectively.

(c) Wheelchairs may include a power-operated vehicle that may be appropriately used as a wheelchair, but only if the vehicle—

(1) Is determined to be necessary on the basis of the individual's medical and physical condition;

(2) Meets any safety requirements specified by CMS; and

(3) Except as provided in paragraph (c)(2) of this section, is ordered in writing by a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology, the written order is furnished to the supplier before the delivery of the vehicle to the beneficiary, and the beneficiary requires the vehicle and is capable of using it.

(4) A written prescription from the beneficiary's physician is acceptable for ordering a power-operated vehicle if a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology is not reasonably accessible. For example, if travel to the specialist would be more than one day's trip from the beneficiary's home or if the beneficiary's medical condition precluded travel to the nearest available specialist, these circumstances would satisfy the ''not reasonably accessible'' requirement.

(d) Medicare Part B pays for medically necessary equipment that is used for treatment of decubitus ulcers if—

(1) The equipment is ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the equipment; and

(2) The prescribing physician has specified in the prescription that he or she will be supervising the use of the equipment in connection with the course of treatment.

(e) Medicare Part B pays for a medically necessary seat-lift if it—

(1) Is ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the seat-lift;

(2) Is for a beneficiary who has a diagnosis designated by CMS as requiring a seat-lift; and

(3) Meets safety requirements specified by CMS.

(f) Medicare Part B pays for transcutaneous electrical nerve stimulator units that are—

(1) Determined to be medically necessary; and

(2) Ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the unit to the beneficiary.

(g) As a requirement for payment, CMS may determine through carrier instructions, or carriers may determine that an item of durable medical equipment requires a written physician order before delivery of the item.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 57688, Dec. 7, 1992; 58 FR 30668, May 26, 1993]

EFFECTIVE DATE NOTE: At 70 FR 50946, Aug. 26, 2005, § 410.38 was amended by revising paragraph (c), effective October 25, 2005. For the convenience of the user, the revised text is set forth as follows:

§ 410.38 Durable medical equipment: Scope and conditions.

* * * * *

(c) *Power mobility devices (PMDs).* (1) *Definitions.* For the purposes of this paragraph (c), the following definitions apply:

Physician has the same meaning as in section 1861(r)(1) of the Act.

Power mobility device means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home.

Prescription means a written order completed by the physician or treating practitioner who performed the face-to-face examination and that includes, the beneficiary's name, the date of the face-to-face examination, the diagnoses and conditions that the PMD is expected to modify, a description of the item (for example, a narrative description of the specific type of PMD), the length of need, and the physician or treating practitioner's signature and the date the prescription was written.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5) of the Act, who has conducted a face-to-face examination of the beneficiary.

Supplier means a durable medical equipment (DME) supplier.

(2) *Conditions of payment.* Medicare Part B pays for a power mobility device if the physician or treating practitioner, as defined in paragraph (c)(1) of this section:

(i) Conducts a face-to-face examination of the beneficiary for the purpose of evaluating and treating the beneficiary for his or her medical condition and determining the medical necessity for the PMD as part of an appropriate overall treatment plan;

(ii) Writes a prescription, as defined in paragraph (c)(1) of this section, which is provided to the beneficiary or supplier, and is received by the supplier within 30 days of the face-to-face examination.

(iii) Provides supporting documentation, including pertinent parts of the beneficiary's medical record (*e.g.*, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans and/or other information as may be appropriate) that supports the medical necessity for the power mobility device, which is received by the supplier within 30 days after the face-to-face examination.

(3) *Exceptions.* (i) Beneficiaries discharged from a hospital do not need to receive a separate face-to-face examination as long as the physician or treating practitioner who performed the face-to-face examination of the beneficiary in the hospital issues a PMD prescription and supporting documentation that is received by the supplier within 30 days after the date of discharge.

(ii) Accessories for PMDs may be ordered by the physician or treating practitioner without conducting a face-to-face examination of the beneficiary.

(4) *Dispensing a power mobility device.* Suppliers may not dispense a PMD to a beneficiary until the PMD prescription and the supporting documentation have been received from the physician or treating practitioner who performed the face-to-face examination of the beneficiary. Such documents must be received within 30 days after the date of the face-to-face examination.

(5) *Documentation.* (i) A supplier must maintain the prescription and the supporting documentation provided by the physician or treating practitioner and make them available to CMS and its agents upon request.

(ii) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the power mobility device.

(6) *Safety requirements.* The PMD must meet any safety requirements specified by CMS.

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§ 410.39 Prostate cancer screening tests: Conditions for and limitations on coverage.

(a) *Definitions.* As used in this section, the following definitions apply:

(1) *Prostate cancer screening tests* means any of the following procedures furnished to an individual for the purpose of early detection of prostate cancer:

(i) A screening digital rectal examination.

(ii) A screening prostate-specific antigen blood test.

(iii) For years beginning after 2002, other procedures CMS finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and other factors CMS considers appropriate.

(2) *A screening digital rectal examination* means a clinical examination of an individual's prostate for nodules or other abnormalities of the prostate.

(3) *A screening prostate-specific antigen blood test* means a test that measures the level of prostate-specific antigen in an individual's blood.

(4) A physician for purposes of this provision means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.

(5) A physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife for purposes of this provision means a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (as defined in sections 1861(aa) and 1861(gg) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.

(b) *Condition for coverage of screening digital rectal examinations.* Medicare Part B pays for a screening digital rectal examination if it is performed by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to perform this service under State law.

(c) *Limitation on coverage of screening digital rectal examinations.* (1) Payment may not be made for a screening digital rectal examination performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening digital rectal examination only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening digital rectal examination was performed.

(d) *Condition for coverage of screening prostate-specific antigen blood tests.* Medicare Part B pays for a screening prostate-specific antigen blood test if it is ordered by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to order this test under State law.

(e) *Limitation on coverage of screening prostate-specific antigen blood test.* (1) Payment may not be made for a screening prostate-specific antigen blood test performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening prostate-specific antigen blood test only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening prostate-specific antigen blood test was performed.

[64 FR 59440, Nov. 2, 1999, as amended at 65 FR 19331, Apr. 11, 2000]

§ 410.40 Coverage of ambulance services.

(a). *Basic rules.* Medicare Part B covers ambulance services if the following conditions are met:

(1) The supplier meets the applicable vehicle, staff, and billing and reporting requirements of § 410.41 and the service meets the medical necessity and origin and destination requirements of paragraphs (d) and (e) of this section.

(2) Medicare Part A payment is not made directly or indirectly for the services.

(b) *Levels of service.* Medicare covers the following levels of ambulance service, which are defined in § 414.605 of this chapter:

(1) Basic life support (BLS) (emergency and nonemergency).

(2) Advanced life support, level 1 (ALS1) (emergency and nonemergency).

(3) Advanced life support, level 2 (ALS2).

(4) Paramedic ALS intercept (PI).

(5) Specialty care transport (SCT).

(6) Fixed wing transport (FW).

(7) Rotary wing transport (RW).

(c) *Paramedic ALS intercept services.* Paramedic ALS intercept services must meet the following requirements:

(1) Be furnished in an area that is designated as a rural area by any law or regulation of the State or that is located in a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith Modification). (The Goldsmith Modification is a methodology to identify small towns and rural areas within large metropolitan counties that are isolated from central areas by distance or other features.)

(2) Be furnished under contract with one or more volunteer ambulance services that meet the following conditions:

(i) Are certified to furnish ambulance services as required under § 410.41.

(ii) Furnish services only at the BLS level.

(iii) Be prohibited by State law from billing for any service.

(3) Be furnished by a paramedic ALS intercept supplier that meets the following conditions:

(i) Is certified to furnish ALS services as required in § 410.41(b)(2).

(ii) Bills all the recipients who receive ALS intercept services fro the entity, regardless of whether or not those recipients are Medicare beneficiaries.

(d) *Medical necessity requirements*—(1) *General rule.* Medicare covers ambulance services, including fixed wing and rotary wing ambulance services, only if they are furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary. Nonemergency transportation by ambulance is appropriate if either: the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation. It is one factor that is considered in medical necessity determinations. For a beneficiary to be considered bed-confined, the following criteria must be met:

(i) The beneficiary is unable to get up from bed without assistance.

(ii) The beneficiary is unable to ambulate.

(iii) The beneficiary is unable to sit in a chair or wheelchair.

(2) *Special rule for nonemergency, scheduled, repetitive ambulance services.* Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (d)(1) of this section are met. The physician's order must be dated no earlier than 60 days before the date the service is furnished.

(3) *Special rule for nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis.* Medicare covers medically necessary nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis under one of the following circumstances:

(i) For a resident of a facility who is under the care of a physician if the ambulance provider or supplier obtains a written order from the beneficiary's attending physician, within 48 hours after the transport, certifying that the medical necessity requirements of paragraph (d)(1) of this section are met.

(ii) For a beneficiary residing at home or in a facility who is not under the direct care of a physician. A physician certification is not required.

(iii) If the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, a signed certification statement must be obtained from either the physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), registered nurse (RN), or discharge planner, who has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished. This individual must be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported. Medicare regulations for PAs, NPs, and CNSs apply and all applicable State licensure laws apply; or,

(iv) If the ambulance provider or supplier is unable to obtain the required certification within 21 calendar days following the date of the service, the ambulance supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (d)(3)(iii) of this section.

(v) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the signed certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

(e) *Origin and destination requirements.* Medicare covers the following ambulance transportation:

(1) From any point of origin to the nearest hospital, CAH, or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

(2) From a hospital, CAH, or SNF to the beneficiary's home.

(3) From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip.

(4) For a beneficiary who is receiving renal dialysis for treatment of ESRD, from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

(f) *Specific limits on coverage of ambulance services outside the United States.* If services are furnished outside the United States, Medicare Part B covers ambulance transportation to a foreign hospital only in conjunction with the beneficiary's admission for medically necessary inpatient services as specified in subpart H of part 424 of this chapter.

[64 FR 3648, Jan. 25, 1999, as amended at 65 FR 13914, Mar. 15, 2000; 67 FR 9132, Feb. 27, 2002]

§ 410.41 Requirements for ambulance suppliers.

(a) *Vehicle.* A vehicle used as an ambulance must meet the following requirements:

(1) Be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all State and local laws governing an emergency transportation vehicle.

(2) Be equipped with emergency warning lights and sirens, as required by State or local laws.

(3) Be equipped with telecommunications equipment as required by State or local law to include, at a minimum, one two-way voice radio or wireless telephone.

(4) Be equipped with a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving emergency medical equipment as required by State or local laws.

(b) *Vehicle staff—(1) BLS vehicles.* A vehicle furnishing ambulance services must be staffed by at least two people, one of whom must meet the following requirements:

(i) Be certified as an emergency medical technician by the State or local authority where the services are furnished.

(ii) Be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

(2) *ALS vehicles*. In addition to meeting the vehicle staff requirements of paragraph (b)(1) of this section, one of the two staff members must be certified as a paramedic or an emergency medical technician, by the State or local authority where the services are being furnished, to perform one or more ALS services.

(c) *Billing and reporting requirements*. An ambulance supplier must comply with the following requirements:

(1) Bill for ambulance services using CMS-designated procedure codes to describe origin and destination and indicate on claims form that the physician certification is on file.

(2) Upon a carrier's request, complete and return the ambulance supplier form designated by CMS and provide the Medicare carrier with documentation of compliance with emergency vehicle and staff licensure and certification requirements in accordance with State and local laws.

(3) Upon a carrier's request, provide additional information and documentation as required.

[64 FR 3648, Jan. 25, 1999]

§ 410.42 Limitations on coverage of certain services furnished to hospital outpatients.

(a) *General rule*. Except as provided in paragraph (b) of this section, Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient (as defined in § 410.2) during an encounter (as defined in § 410.2) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to its patients. As used in this paragraph, the term ''hospital'' includes a CAH.

(b) *Exception*. The limitations stated in paragraph (a) of this section do not apply to the following services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in § 410.69.

(7) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

[65 FR 18536, Apr. 7, 2000]

§ 410.43 Partial hospitalization services: Conditions and exclusions.

(a) Partial hospitalization services are services that—

(1) Are reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(2) Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and

(3) Include any of the following:

(i) Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law.

(ii) Occupational therapy requiring the skills of a qualified occupational therapist.

(iii) Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.

(iv) Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.

(v) Individualized activity therapies that are not primarily recreational or diversionary.

(vi) Family counseling, the primary purpose of which is treatment of the individual's condition.

(vii) Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.

(viii) Diagnostic services.

(b) The following services are separately covered and not paid as partial hospitalization services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

[59 FR 6577, Feb. 11, 1994, as amended at 65 FR 18536, Apr. 7, 2000]

§ 410.45 Rural health clinic services: Scope and conditions.

(a) Medicare Part B pays for the following rural health clinic services, if they are furnished in accordance with the requirements and conditions specified in part 405, subpart X, and part 491 of this chapter:

(1) Physicians' services.

(2) Services and supplies furnished as an incident to physicians' professional services.

(3) Nurse practitioner and physician assistant services.

(4) Services and supplies furnished as an incident to nurse practitioners' or physician assistants' services.

(5) Visiting nurse services.

(b) Medicare pays for rural health clinic services when they are furnished at the clinic, at a hospital or other medical facility, or at the beneficiary's place of residence.

§ 410.46 Physician and other practitioner services furnished in or at the direction of an IHS or Indian tribal hospital or clinic: Scope and conditions.

(a) Medicare Part B pays, in accordance with the physician fee schedule, for services furnished in or at the direction of a hospital or outpatient clinic (provider-based or free-standing) that is operated by the Indian Health Service (IHS) or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act). These services are subject to the same situations, terms, and conditions that would apply if the services were furnished in or at the direction of a hospital or clinic that is not operated by IHS or by an Indian tribe or tribal organization. Payments include health professional shortage areas incentive payments when the requirements for these incentive payments in § 414.42 of this chapter are met.

(b) Payment is not made under this section to the extent that Medicare otherwise pays for the same services under other provisions.

(c) Payment is made under these provisions for the following services:

(1) Services for which payment is made under the physician fee schedule in accordance with part 414 of this chapter.

(2) Services furnished by non-physician practitioners for which payment under Part B is made under the physician fee schedule.

(3) Services furnished by a physical therapist or occupational therapist, for which payment under Part B is made under the physician fee schedule.

(d) Payments under these provisions will be paid to the IHS or tribal hospital or clinic.

[66 FR 55329, Nov. 1, 2001]

§ 410.50 Institutional dialysis services and supplies: Scope and conditions.

Medicare Part B pays for the following institutional dialysis services and supplies if they are furnished in approved ESRD facilities:

(a) All services, items, supplies, and equipment necessary to perform dialysis and drugs medically necessary in the treatment of the patient for ESRD.

(b) Routine dialysis monitoring tests (i.e., hematocrit and clotting time) used by the facility to monitor the patients' fluids incident to each dialysis treatment, when performed by qualified staff of the facility under the direction of a physician, as provided in § 405.2163(b) of this chapter, even if the facility does not meet the conditions for coverage of services of independent laboratories in subpart M of part 405 of this chapter.

(c) Routine diagnostic tests.

(d) Epoetin (EPO) and its administration.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994]

§ 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to an ESRD patient in his or her home:

(1) Purchase or rental, installation, and maintenance of all dialysis equipment necessary for home dialysis, and reconditioning of this equipment. Dialysis equipment includes, but is not limited to, artificial kidney and automated peritoneal dialysis machines, and support equipment such as blood pumps, bubble detectors, and other alarm systems.

(2) Items and supplies required for dialysis, including (but not limited to) dialyzers, syringes and needles, forceps, scissors, scales, sphygmomanometer with cuff and stethoscope, alcohol wipes, sterile drapes, and rubber gloves.

(3) Home dialysis support services furnished by an approved ESRD facility, including periodic monitoring of the patient's home adaptation, emergency visits by qualified provider or facility personnel, any of the tests specified in paragraphs (b) through (d) of § 410.50, personnel costs associated with the installation and maintenance of dialysis equipment, testing and appropriate treatment of water, and ordering of supplies on an ongoing basis.

(4) On or after July 1, 1991, epoetin (EPO) for use at home by a home dialysis patient and, on or after January 1, 1994, by a dialysis patient, if it has been determined, in accordance with § 405.2163 of this chapter, that the patient is competent to use the drug safely and effectively.

(b) Home dialysis support services specified in paragraph (a)(3) of this section must be furnished in accordance with a written treatment plan that is prepared and reviewed by a team consisting of the individual's physician and other qualified professionals. (Section 405.2137 of this chapter contains specific details.)

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 26959, May 25, 1994]

§ 410.55 Services related to kidney donations: Conditions.

Medicare Part B pays for medical and other health services covered under this subpart that are furnished in connection with a kidney donation—

(a) If the kidney is intended for an individual who has end-stage renal disease and is entitled to Medicare benefits; and

(b) Regardless of whether the donor is entitled to Medicare.

§ 410.56 Screening pelvic examinations.

(a) *Conditions for screening pelvic examinations.* Medicare Part B pays for a screening pelvic examination (including a clinical breast examination) if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act), or by a certified nurse midwife (as defined in section 1861(gg) of the Act), or a physician assistant, nurse practitioner, or clinic nurse specialist (as defined in section 1861(aa) of the Act) who is authorized under State law to perform the examination.

(b) *Limits on coverage of screening pelvic examinations.* The following limitations apply to coverage of screening pelvic examination services:

(1) *General rule.* Except as specified in paragraphs (b)(2) and (b)(3) of this section, payment may be made for a pelvic examination performed on an asymptomatic woman only if the individual has not had a pelvic examination paid for by Medicare during the preceding 23 months following the month in which her last Medicare-covered screening pelvic examination was performed.

(2) *More frequent screening based on high-risk factors.* Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 24 months if the test is performed by a physician or other practitioner specified in paragraph (a) of this section, and there is evidence that the woman is at high risk (on the basis of her medical history or other findings) of developing cervical cancer or vaginal cancer, as determined in accordance with the following risk factors:

(i) High risk factors for cervical cancer:

(A) Early onset of sexual activity (under 16 years of age).

(B) Multiple sexual partners (five or more in a lifetime).

(C) History of a sexually transmitted disease (including HIV infection).

(D) Absence of three negative or any Pap smears within the previous 7 years.

(ii) High risk factor for vaginal cancer: DES (diethylstilbestrol)-exposed daughters of women who took DES during pregnancy.

(3) *More frequent screening for women of childbearing age.* Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 24 months if the test is performed by a physician or other practitioner as specified in paragraph (a) of this section for a woman of childbearing age who has had an examination that indicated the presence of cervical or vaginal cancer or other abnormality during any of the preceding 3 years. The term ''woman of childbearing age'' means a woman who is premenopausal, and has been determined by a physician, or a qualified practitioner, as specified in paragraph (a) of this section, to be of childbearing age, based on her medical history or other findings.

(4) *Limitation applicable to women at high risk and those of childbearing age.* Payment is not made for a screening pelvic examination for women considered to be at high risk (under any of the criteria described in paragraph (b)(2) of this section), or who qualify for coverage under the childbearing provision (under the criteria described in paragraph (b)(3) of this section) more frequently than once every 11 months after the month that the last screening pelvic examination covered by Medicare was performed.

[62 FR 59101, Oct. 31, 1997; 63 FR 4596, Jan. 30, 1998, as amended at 66 FR 55329, Nov. 1, 2001]

§ 410.57 Pneumococcal vaccine and flu vaccine.

(a) Medicare Part B pays for pneumococcal vaccine and its administration when reasonable and necessary for the prevention of disease, if the vaccine is ordered by a doctor of medicine or osteopathy.

(b) Medicare Part B pays for the influenza virus vaccine and its administration.

[63 FR 35066, June 26, 1998]

§ 410.58 Additional services to HMO and CMP enrollees.

Services not usually covered under Medicare Part B may be covered as medical and other health services if they are furnished to an enrollee of an HMO or a CMP and the following conditions are met:

(a) The services are—

(1) Furnished by a physician assistant or nurse practitioner as defined in § 491.2 of this chapter, or are incident to services furnished by such a practitioner; or

(2) Furnished by a clinical psychologist as defined in § 417.416 of this chapter to an enrollee of an HMO or CMP that participates in Medicare under a risk-sharing contract, or are incident to those services.

(b) The services are services that would be covered under Medicare Part B if they were furnished by a physician or as incident to a physician's professional services.

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) *Basic rule.* Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient occupational therapy services only if they are furnished by an individual meeting the qualifications in § 484.4 of this chapter for an occupational therapist or by an appropriately supervised occupational therapy assistant but only under the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of § 410.61.

(3) They are furnished—

(i) By a provider as defined in § 489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By, or under the direct supervision of, an occupational therapist in private practice as described in paragraph (c) of this section; or

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform occupational therapy services within the scope of State law. When an occupational therapy service is provided incident to the service of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to occupational therapy and occupational therapists, except that a license to practice occupational therapy in the State is not required.

(b) *Conditions for coverage of outpatient therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient occupational therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by occupational therapists in private practice.*

(1) *Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient occupational therapy services, each individual occupational therapist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of occupational therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types:

(A) An unincorporated solo practice.

(B) A partnership or unincorporated group practice.

(C) An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated occupational therapy practice.

(D) An employee of a physician group.

(E) An employee of a group that is not a professional corporation.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, that space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, an CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(2) *Supervision of occupational therapy services.* Occupational therapy services are performed by, or under the direct supervision of, an occupational therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services.

(d) *Excluded services.* No service is included as an outpatient occupational therapy service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(e) *Annual limitation on incurred expenses.* (1) Amount of limitation. (i) In 1999, 2000, and 2001, no more than $1,500 of allowable charges incurred in a calendar year for outpatient occupational therapy services are recognized incurred expenses.

(ii) In 2002 and thereafter, the limitation is determined by increasing the limitation in effect in the previous calendar year by the increase in the Medicare Economic Index for the current year.

(iii) The limitation is not applied for services furnished from December 8, 2003 through December 31, 2005.

(2) For purposes of applying the limitation, outpatient occupational therapy includes:

(i) Except as provided in paragraph (e)(3) of this section, outpatient occupational therapy services furnished under this section;

(ii) Outpatient occupational therapy services furnished by a comprehensive outpatient rehabilitation facility;

(iii) Outpatient occupational therapy services furnished by a physician or incident to a physician's service;

(iv) Outpatient occupational therapy services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services.

(3) For purposes of applying the limitation, outpatient occupational therapy services excludes services furnished by a hospital directly or under arrangements.

[63 FR 58906, Nov. 2, 1998, as amended at 67 FR 80040, Dec. 31, 2002; 69 FR 66421, Nov. 15, 2004]

§ 410.60 Outpatient physical therapy services: Conditions.

(a) *Basic rule.* Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient physical therapy services only if they are furnished by an individual meeting the qualifications in § 484.4 of this chapter for a physical therapist or by an appropriately supervised physical therapist assistant but only under the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of § 410.61.

(3) They are furnished—

(i) By a provider as defined in § 489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By, or under the direct supervision of a physical therapist in private practice as described in paragraph (c) of this section; or

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform physical therapy services under State law. When a physical therapy service is provided incident to the service of a physician, physician's assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to physical therapy and physical therapists, except that a license to practice physical therapy in the State is not required.

(b) *Condition for coverage of outpatient physical therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient physical therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise +ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by physical therapists in private practice.* (1) *Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient physical therapy services, each individual physical therapist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of physical therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of physical therapy on a regular basis as an individual, in one of the following practice types:

(A) An unincorporated solo practice.

(B) An unincorporated partnership or unincorporated group practice.

(C) An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated physical therapy practice.

(D) An employee of a physician group.

(E) An employee of a group that is not a professional corporation.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, that space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, a CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(2) *Supervision of physical therapy services.* Physical therapy services are performed by, or under the direct supervision of, a physical therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services.

(d) *Excluded services.* No service is included as an outpatient physical therapy service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(e) *Annual limitation on incurred expenses.* (1) Amount of limitation. (i) In 1999, 2000, and 2001, no more than $1,500 of allowable charges incurred in a calendar year for outpatient physical therapy services are recognized incurred expenses.

(ii) In 2002 and thereafter, the limitation shall be determined by increasing the limitation in effect in the previous calendar year by the increase in the Medicare Economic Index for the current year.

(iii) The limitation is not applied for services furnished from December 8, 2003 through December 31, 2005.

(2) For purposes of applying the limitation, outpatient physical therapy includes:

(i) Except as provided in paragraph (e)(3) of this section, outpatient physical therapy services furnished under this section;

(ii) Except as provided in paragraph (e)(3) of this section outpatient speech-language pathology services furnished under § 410.62;

(iii) Outpatient physical therapy and speech-language pathology services furnished by a comprehensive outpatient rehabilitation facility;

(iv) Outpatient physical therapy and speech-language pathology services furnished by a physician or incident to a physician's service;

(v) Outpatient physical therapy and speech-language pathology services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services.

(3) For purposes of applying the limitation, outpatient physical therapy excludes services furnished by a hospital or CAH directly or under arrangements.

[63 FR 58906, Nov. 2, 1998, as amended at 67 FR 80041, Dec. 31, 2002; 69 FR 66422, Nov. 15, 2004]

§ 410.61 Plan of treatment requirements for outpatient rehabilitation services.

(a) *Basic requirement.* Outpatient rehabilitation services (including services furnished by a qualified physical or occupational therapist in private practice), must be furnished under a written plan of treatment that meets the requirements of paragraphs (b) through (e) of this section.

(b) *Establishment of the plan.* The plan is established before treatment is begun by one of the following:

(1) A physician.

(2) A physical therapist who furnishes the physical therapy services.

(3) A speech-language pathologist who furnishes the speech-language pathology services.

(4) An occupational therapist who furnishes the occupational therapy services.

(5) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy,

occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals.

(d) *Changes in the plan.* Any changes in the plan—

(1) Are made in writing and signed by one of the following:

(i) The physician.

(ii) The physical therapist who furnishes the physical therapy services.

(iii) The occupational therapist that furnishes the occupational therapy services.

(iv) The speech-language pathologist who furnishes the speech-language pathology services.

(v) A registered professional nurse or a staff physician, in accordance with oral orders from the physician, physical therapist, occupational therapist, or speech-language pathologist who furnishes the services.

(vi) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(2) The changes are incorporated in the plan immediately.

(e) *Review of the plan.* (1) The physician reviews the plan as often as the individual's condition requires, but at least every 30 days.

(2) Each review is dated and signed by the physician who performs it.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 54 FR 38680, Sept. 20, 1989; 54 FR 46614, Nov. 6, 1989. Redesignated at 56 FR 8854, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 63 FR 58907, Nov. 2, 1998; 67 FR 80040, Dec. 31, 2002]

§ 410.62 Outpatient speech-language pathology services: Conditions and exclusions.

(a) *Basic rule.* Except as specified in paragraph (a)(3)(ii) of this section, Medicare Part B pays for outpatient speech-language pathology services only if they are furnished by an individual who meets the qualifications for a speech-language pathologist in § 484.4 of this chapter and only under the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine or osteopathy.

(2) They are furnished under a written plan of treatment that—

(i) Is established by a physician or, effective January 1, 1982, by either a physician or the speech-language pathologist who provides the services to the particular individual;

(ii) Is periodically reviewed by a physician; and

(iii) Meets the requirements of § 410.61.

(3) They are furnished—

(i) By a provider as defined in § 489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform speech-language pathology services under State law. When a speech-language pathology service is provided incident to the services of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to speech-language pathology and speech-language pathologists, except that a license to practice speech-language pathology services in the State is not required.

(b) *Condition for coverage of outpatient speech-language pathology services to certain inpatients of a hospital, CAH, or SNF.* Medicare Part B pays for outpatient speech-language pathology services furnished to an inpatient of a hospital, CAH, or SNF who requires the services but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Excluded services.* No service is included as an outpatient speech-language pathology service if it is not included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(d) *Limitation.* After 1998, outpatient speech-language pathology services are subject to the limitation in § 410.60(e).

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20. 1991; 58 FR 30668, May 26, 1993; 63 FR 58907, Nov. 2, 1998; 69 FR 66422, Nov. 15, 2004]

§ 410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

Notwithstanding the exclusion from coverage of vaccines (see § 405.310 of this chapter) and self-administered drugs (see § 410.29), the following services are included as medical and other health services covered under § 410.10, subject to the specified conditions:

(a) *Hepatitis B vaccine: Conditions.* Effective September 1, 1984, hepatitis B vaccinations that are reasonable and necessary for the prevention of illness for those individuals who are at high or intermediate risk of contracting hepatitis B as listed below:

(1) *High risk groups.* (i) End-Stage Renal Disease (ESRD) patients;

(ii) Hemophiliacs who receive Factor VIII or IX concentrates;

(iii) Clients of institutions for the mentally retarded;

(iv) Persons who live in the same household as a hepatitis B carrier;

(v) Homosexual men;

(vi) Illicit injectable drug abusers; and

(vii) Pacific Islanders (that is, those Medicare beneficiaries who reside on Pacific islands under U.S. jurisdiction, other than residents of Hawaii).

(2) *Intermediate risk groups.* (i) Staff in institutions for the mentally retarded and classroom employees who work with mentally retarded persons;

(ii) Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work (including workers who work outside of a hospital and have frequent contact with blood or other infectious secretions); and

(iii) Heterosexually active persons with multiple sexual partners (that is, those Medicare beneficiaries who have had at least two documented episodes of sexually transmitted diseases within the preceding 5 years).

(3) *Exception.* Individuals described in paragraphs (a) (1) and (2) of this section are not considered at high or intermediate risk of contracting hepatitis B if they have undergone a prevaccination screening and have been found to be currently positive for antibodies to hepatitis B.

(b) *Blood clotting factors: Conditions.* Effective July 18, 1984, blood clotting factors to control bleeding for hemophilia patients competent to use these factors without medical or other supervision, and items related to the administration of those factors. The amount of clotting factors covered under this provision is determined by the carrier based on the historical utilization pattern or profile developed by the carrier for each patient, and based on consideration of the need for a reasonable reserve supply to be kept in the home in the event of emergency or unforeseen circumstance.

(c) *Blood clotting factors: Furnishing Fee.* (1) Effective January 1, 2005, a furnishing fee of $0.14 per unit of clotting factor is paid to entities that furnish blood clotting factors unless the costs associated with furnishing the clotting factor are paid through another payment system, for example, hospitals that furnish clotting factor to patients during a Part A covered inpatient hospital stay.

(2) The furnishing fee for blood clotting factors furnished in 2006 or a subsequent year is be equal to the furnishing fee paid the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

[55 FR 22790, June 4, 1990; 55 FR 31186, Aug. 1, 1990, as amended at 69 FR 66422, Nov. 15, 2004]

§ 410.66 Emergency outpatient services furnished by a nonparticipating hospital and services furnished in Mexico or Canada.

Conditions for payment of emergency outpatient services furnished by a nonparticipating U.S. hospital and for services furnished in Mexico or Canada are set forth in subparts G and H of part 424 of this chapter.

[53 FR 6634, Mar. 1, 1988; 53 FR 12945, Apr. 20, 1988]

§ 410.68 Antigens: Scope and conditions.

Medicare Part B pays for—

(a) Antigens that are furnished as services incident to a physician's professional services; or

(b) A supply of antigen sufficient for not more than 12 months that is—

(1) Prepared for a patient by a doctor of medicine or osteopathy who has examined the patient and developed a

plan of treatment including dosage levels; and

(2) Administered—

(i) In accord with the plan of treatment developed by the doctor of medicine or osteopathy who prepared the antigen; and

(ii) By a doctor of medicine or osteopathy or by a properly instructed person under the supervision of a doctor of medicine or osteopathy.

[54 FR 4026, Jan. 27, 1989, as amended at 65 FR 65440, Nov. 1, 2000]

§ 410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.

(a) *Basic rule.* Medicare Part B pays for anesthesia services and related care furnished by a certified registered nurse anesthetist or an anesthesiologist's assistant who is legally authorized to perform the services by the State in which the services are furnished.

(b) *Definitions.* For purposes of this part—

Anesthesiologist's assistant means a person who—

(1) Works under the direction of an anesthesiologist;

(2) Is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and

(3) Is a graduate of a medical school-based anesthesiologist's assistant educational program that—

(A) Is accredited by the Committee on Allied Health Education and Accreditation; and

(B) Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

Anesthetist includes both an anesthesiologist's assistant and a certified registered nurse anesthetist.

Certified registered nurse anesthetist means a registered nurse who:

(1) Is licensed as a registered professional nurse by the State in which the nurse practices;

(2) Meets any licensure requirements the State imposes with respect to nonphysician anesthetists;

(3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) Meets the following criteria:

(i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) Is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.

[57 FR 33896, July 31, 1992]

§ 410.71 Clinical psychologist services and services and supplies incident to clinical psychologist services.

(a) *Included services.* (1) Medicare Part B covers services furnished by a clinical psychologist, who meets the requirements specified in paragraph (d) of this section, that are within the scope of his or her State license, if the services would be covered if furnished by a physician or as an incident to a physician's services.

(2) Medicare Part B covers services and supplies furnished as an incident to the services of a clinical psychologist if the following requirements are met:

(i) The services and supplies would be covered if furnished by a physician or as an incident to a physician's services.

(ii) The services or supplies are of the type that are commonly furnished in a physician's or clinical psychologist's office and are either furnished without charge or are included in the physician's or clinical psychologist's bill.

(iii) The services are an integral, although incidental, part of the professional services performed by the clinical psychologist.

(iv) The services are performed under the direct supervision of the clinical psychologist. For example, when services are performed in the clinical psychologist's office, the clinical psychologist must be present in the office

suite and immediately available to provide assistance and direction throughout the time the service is being performed.

(v) The individual performing the service must be an employee of either the clinical psychologist or the legal entity that employs the supervising clinical psychologist, under the common law control test of the Act as more fully set forth in 20 CFR 404.1007.

(b) *Application of mental health treatment limitation.* The treatment services of a clinical psychologist and services and supplies furnished as an incident to those services are subject to the limitation on payment for outpatient mental health treatment services set forth in § 410.155.

(c) *Payment for consultations.* A clinical psychologist or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph (e) of this section.

(d) *Qualifications.* For purposes of this subpart, a clinical psychologist is an individual who—

(1) Holds a doctoral degree in psychology; and

(2) Is licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

(e) *Agreement to consult.* A clinical psychologist who bills Medicare Part B must agree to meet the requirements of paragraphs (e)(1) through (e)(3) of this section. The clinical psychologist's signature on a Medicare provider/supplier enrollment form indicates his or her agreement.

(1) Unless the beneficiary's primary care or attending physician has referred the beneficiary to the clinical psychologist, to inform the beneficiary that it is desirable for the clinical psychologist to consult with the beneficiary's attending or primary care physician (if the beneficiary has such a physician) to consider any conditions contributing to the beneficiary's symptoms.

(2) If the beneficiary assents to the consultation, in accordance with accepted professional ethical norms and taking into consideration patient confidentiality—

(i) To attempt, within a reasonable time after receiving the consent, to consult with the physician; and

(ii) If attempts to consult directly with the physician are not successful, to notify the physician, within a reasonable time, that he or she is furnishing services to the beneficiary.

(3) Unless the primary care or attending physician referred the beneficiary to the clinical psychologist, to document, in the beneficiary's medical record, the date the patient consented or declined consent to consultation, the date of consultation, or, if attempts to consult did not succeed, the date and manner of notification to the physician.

[63 FR 20128, Apr. 23, 1998]

§ 410.73 Clinical social worker services.

(a) *Definition: clinical social worker.* For purposes of this part, a clinical social worker is defined as an individual who—

(1) Possesses a master's or doctor's degree in social work;

(2) After obtaining the degree, has performed at least 2 years of supervised clinical social work; and

(3) Either is licensed or certified as a clinical social worker by the State in which the services are performed or, in the case of an individual in a State that does not provide for licensure or certification as a clinical social worker—

(i) Is licensed or certified at the highest level of practice provided by the laws of the State in which the services are performed; and

(ii) Has completed at least 2 years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's degree level social worker in an appropriate setting such as a hospital, SNF, or clinic.

(b) *Covered clinical social worker services.* Medicare Part B covers clinical social worker services.

(1) *Definition.* ''Clinical social worker services'' means, except as specified in paragraph (b)(2) of this section, the

services of a clinical social worker furnished for the diagnosis and treatment of mental illness that the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which the services are performed. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception*. The following services are not clinical social worker services for purposes of billing Medicare Part B:

(i) Services furnished by a clinical social worker to an inpatient of a Medicare-participating hospital.

(ii) Services furnished by a clinical social worker to an inpatient of a Medicare-participating SNF.

(iii) Services furnished by a clinical social worker to a patient in a Medicare-participating dialysis facility if the services are those required by the conditions for coverage for ESRD facilities under § 405.2163 of this chapter.

(c) *Agreement to consult*. A clinical social worker must comply with the consultation requirements set forth at § 410.71(f) (reading ''clinical psychologist'' as ''clinical social worker'').

(d) *Prohibited billing*. (1) A clinical social worker may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A clinical social worker or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph (c) of this section.

[63 FR 20128, Apr. 23, 1998]

§ 410.74 Physician assistants' services.

(a) *Basic rule*. Medicare Part B covers physician assistants' services only if the following conditions are met:

(1) The services would be covered as physicians' services if furnished by a physician (a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act).

(2) The physician assistant—

(i) Meets the qualifications set forth in paragraph (c) of this section;

(ii) Is legally authorized to perform the services in the State in which they are performed;

(iii) Performs services that are not otherwise precluded from coverage because of a statutory exclusion;

(iv) Performs the services under the general supervision of a physician (The supervising physician need not be physically present when the physician assistant is performing the services unless required by State law; however, the supervising physician must be immediately available to the physician assistant for consultation.);

(v) Furnishes services that are billed by the employer of a physician assistant; and

(vi) Performs the services—

(A) In all settings in either rural and urban areas; or

(B) As an assistant at surgery.

(b) *Services and supplies furnished incident to a physician assistant's services*. Medicare covers services and supplies (including drugs and biologicals that cannot be self-administered) that are furnished incident to the physician assistant's services described in paragraph (a) of this section. These services and supplies are covered only if they—

(1) Would be covered if furnished by a physician or as incident to the professional services of a physician;

(2) Are the type that are commonly furnished in a physician's office and are either furnished without charge or are included in the bill for the physician assistants' services;

(3) Are, although incidental, an integral part of the professional service performed by the physician;

(4) Are performed under the direct supervision of the physician assistant (that is, the physician assistant is physically present and immediately available); and

(5) Are performed by the employee of a physician assistant or an entity that employs both the physician assistant and the person providing the services.

(c) *Qualifications*. For Medicare Part B coverage of his or her services, a physician assistant must meet all of the following conditions:

(1) Have graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or

(2) Have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and

(3) Be licensed by the State to practice as a physician assistant.

(d) *Professional services.* Physician assistants can be paid for professional services only if the services have been professionally performed by them and no facility or other provider charges for the service or is paid any amount for the furnishing of those professional services.

(1) Supervision of other nonphysician staff by a physician assistant does not constitute personal performance of a professional service by the physician assistant.

(2) The services are provided on an assignment-related basis, and the physician assistant may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the physician assistant must make the appropriate refund to the beneficiary.

[63 FR 58907, Nov. 2, 1998; 64 FR 25457, May 12, 1999]

§ 410.75 Nurse practitioners' services.

(a) *Definition.* As used in this section, the term ''physician'' means a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act.

(b) *Qualifications.* For Medicare Part B coverage of his or her services, a nurse practitioner must—(1)(i) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; *and*

(ii) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; *or*

(2) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; or

(3) Be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section; or

(4) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section.

(c) *Services.* Medicare Part B covers nurse practitioners' services in all settings in both rural and urban areas, only if the services would be covered if furnished by a physician and the nurse practitioner—

(1) Is legally authorized to perform them in the State in which they are performed;

(2) Is not performing services that are otherwise excluded from coverage because of one of the statutory exclusions; and

(3) Performs them while working in collaboration with a physician.

(i) Collaboration is a process in which a nurse practitioner works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed.

(ii) In the absence of State law governing collaboration, collaboration is a process in which a nurse practitioner has a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by nurse practitioners documenting the nurse practitioners' scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Nurse practitioners must document this collaborative process with physicians.

(iii) The collaborating physician does not need to be present with the nurse practitioner when the services are furnished or to make an independent evaluation of each patient who is seen by the nurse practitioner.

(d) *Services and supplies incident to a nurse practitioners' services.* Medicare

Part B covers services and supplies (including drugs and biologicals that cannot be self-administered) incident to a nurse practitioner's services that meet the requirements in paragraph (c) of this section. These services and supplies are covered only if they—

(1) Would be covered if furnished by a physician or as incident to the professional services of a physician;

(2) Are of the type that are commonly furnished in a physician's office and are either furnished without charge or are included in the bill for the nurse practitioner's services;

(3) Although incidental, are an integral part of the professional service performed by the nurse practitioner; and

(4) Are performed under the direct supervision of the nurse practitioner (that is, the nurse practitioner must be physically present and immediately available).

(e) *Professional services.* Nurse practitioners can be paid for professional services only when the services have been personally performed by them and no facility or other provider charges, or is paid, any amount for the furnishing of the professional services.

(1) Supervision of other nonphysician staff by a nurse practitioner does not constitute personal performance of a professional service by a nurse practitioner.

(2) The services are provided on an assignment-related basis, and a nurse practitioner may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the nurse practitioner must make the appropriate refund to the beneficiary.

[63 FR 58908, Nov. 2, 1998; 64 FR 25457, May 12, 1999, as amended at 64 FR 59440, Nov. 2, 1999]

§ 410.76 Clinical nurse specialists' services.

(a) *Definition.* As used in this section, the term ''physician'' means a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act.

(b) *Qualifications.* For Medicare Part B coverage of his or her services, a clinical nurse specialist must—

(1) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;

(2) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and

(3) Be certified as a clinical nurse specialist by a national certifying body that has established standards for clinical nurse specialists and that is approved by the Secretary.

(c) *Services.* Medicare Part B covers clinical nurse specialists' services in all settings in both rural and urban areas only if the services would be covered if furnished by a physician and the clinical nurse specialist—

(1) Is legally authorized to perform them in the State in which they are performed;

(2) Is not performing services that are otherwise excluded from coverage by one of the statutory exclusions; and

(3) Performs them while working in collaboration with a physician.

(i) Collaboration is a process in which a clinical nurse specialist works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed.

(ii) In the absence of State law governing collaboration, collaboration is a process in which a clinical nurse specialist has a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by clinical nurse specialists documenting the clinical nurse specialists' scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Clinical nurse specialists must document this collaborative process with physicians.

(iii) The collaborating physician does not need to be present with the clinical nurse specialist when the services are furnished, or to make an independent evaluation of each patient who is seen by the clinical nurse specialist.

(d) *Services and supplies furnished incident to clinical nurse specialists' services.* Medicare Part B covers services and supplies (including drugs and

biologicals that cannot be self-administered) incident to a clinical nurse specialist's services that meet the requirements in paragraph (c) of this section. These services and supplies are covered only if they—

(1) Would be covered if furnished by a physician or as incident to the professional services of a physician;

(2) Are of the type that are commonly furnished in a physician's office and are either furnished without charge or are included in the bill for the clinical nurse specialist's services;

(3) Although incidental, are an integral part of the professional service performed by the clinical nurse specialist; and

(4) Are performed under the direct supervision of the clinical nurse specialist (that is, the clinical nurse specialist must be physically present and immediately available).

(e) *Professional services.* Clinical nurse specialists can be paid for professional services only when the services have been personally performed by them and no facility or other provider charges, or is paid, any amount for the furnishing of the professional services.

(1) Supervision of other nonphysician staff by clinical nurse specialists does not constitute personal performance of a professional service by clinical nurse specialists.

(2) The services are provided on an assignment-related basis, and a clinical nurse specialist may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the clinical nurse specialist must make the appropriate refund to the beneficiary.

[63 FR 58908, Nov. 2, 1998, as amended at 67 FR 80040, Dec. 31, 2002]

§ 410.77 Certified nurse-midwives' services: Qualifications and conditions.

(a) *Qualifications.* For Medicare coverage of his or her services, a certified nurse-midwife must:

(1) Be a registered nurse who is legally authorized to practice as a nurse-midwife in the State where services are performed;

(2) Have successfully completed a program of study and clinical experience for nurse-midwives that is accredited by an accrediting body approved by the U.S. Department of Education; and

(3) Be certified as a nurse-midwife by the American College of Nurse-Midwives or the American College of Nurse-Midwives Certification Council.

(b) *Services.* A certified nurse-midwife's services are services furnished by a certified nurse-midwife and services and supplies furnished as an incident to the certified nurse-midwife's services that—

(1) Are within the scope of practice authorized by the law of the State in which they are furnished and would otherwise be covered if furnished by a physician or as an incident to a physician's service; and

(2) Unless required by State law, are provided without regard to whether the certified nurse-midwife is under the supervision of, or associated with, a physician or other health care provider.

(c) *Incident to services: Basic rule.* Medicare covers services and supplies furnished incident to the services of a certified nurse-midwife, including drugs and biologicals that cannot be self-administered, if the services and supplies meet the following conditions:

(1) They would be covered if furnished by a physician or as incident to the professional services of a physician.

(2) They are of the type that are commonly furnished in a physician's office and are either furnished without charge or are included in the bill for the certified nurse-midwife's services.

(3) Although incidental, they are an integral part of the professional service performed by the certified nurse-midwife.

(4) They are furnished under the direct supervision of a certified nurse-midwife (that is, the midwife is physically present and immediately available).

(d) *Professional services.* A nurse-midwife can be paid for professional services only when the services have been performed personally by the nurse-midwife.

(1) Supervision of other nonphysician staff by a nurse-midwife does not constitute personal performance of a professional service by the nurse-midwife.

(2) The service is provided on an assignment-related basis, and a nurse-

midwife may not charge a beneficiary for a service not payable under this provision. If the beneficiary has made payment for a service, the nurse-midwife must make the appropriate refund to the beneficiary.

(3) A nurse-midwife may provide services that he or she is legally authorized to perform under State law as a nurse-midwife, if the services would otherwise be covered by the Medicare program when furnished by a physician or incident to a physicians' professional services.

[63 FR 58909, Nov. 2, 1998]

§ 410.78 Telehealth services.

(a) *Definitions*. For the purposes of this section the following definitions apply:

(1) *Asynchronous store and forward technologies* means the transmission of a patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs visualized by a telecommunications system must be specific to the patient's medical condition and adequate for furnishing or confirming a diagnosis and or treatment plan. Dermatological photographs, for example, a photograph of a skin lesion, may be considered to meet the requirement of a single media format under this provision.

(2) *Distant site* means the site at which the physician or practitioner delivering the service is located at the time the service is provided via a telecommunications system.

(3) *Interactive telecommunications system* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

(4) *Originating site* means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous store and forward telecommunications technologies, the only originating sites are Federal telemedicine demonstration programs conducted in Alaska or Hawaii.

(b) *General rule*. Medicare Part B pays for office and other outpatient visits, professional consultation, psychiatric diagnostic interview examination, individual psychotherapy, pharmacologic management and end stage renal disease related services included in the monthly capitation payment (except for one visit per month to examine the access site) furnished by an interactive telecommunications system if the following conditions are met:

(1) The physician or practitioner at the distant site must be licensed to furnish the service under State law. The physician or practitioner at the distant site who is licensed under State law to furnish a covered telehealth service described in this section may bill, and receive payment for, the service when it is delivered via a telecommunications system.

(2) The practitioner at the distant site is one of the following:

(i) A physician as described in § 410.20.

(ii) A physician assistant as described § 410.74.

(iii) A nurse practitioner as described in § 410.75.

(iv) A clinical nurse specialist as described in § 410.76.

(v) A nurse-midwife as described in § 410.77.

(vi) A clinical psychologist as described in § 410.71.

(vii) A clinical social worker as described in § 410.73.

(3) The services are furnished to a beneficiary at an originating site, which is one of the following:

(i) The office of a physician or practitioner.

(ii) A critical access hospital (as described in section 1861(mm)(1) of the Act).

(iii) A rural health clinic (as described in section 1861(aa)(2) of the Act).

(iv) A Federally qualified health center (as defined in section 1861(aa)(4) of the Act).

(v) A hospital (as defined in section 1861(e) of the Act).

(4) Originating sites must be located in either a rural health professional shortage area as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) or in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act. Entities participating in a Federal telemedicine demonstration project that have been approved by, or receive funding from, the Secretary as of December 31, 2000 qualify as an eligible originating site regardless of geographic location.

(5) The medical examination of the patient is under the control of the physician or practitioner at the distant site.

(c) *Telepresenter not required.* A telepresenter is not required as a condition of payment unless a telepresenter is medically necessary as determined by the physician or practitioner at the distant site.

(d) *Exception to the interactive telecommunications system requirement.* For Federal telemedicine demonstration programs conducted in Alaska or Hawaii only, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system.

(e) *Limitation.* A clinical psychologist and a clinical social worker may bill and receive payment for individual psychotherapy via a telecommunications system, but may not seek payment for medical evaluation and management services.

(f) *Process for adding or deleting services.* Changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process.

[66 FR 55330, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2002; 69 FR 66423, Nov. 15, 2004]

Subpart C—Home Health Services Under SMI

§ 410.80 Applicable rules.

Home health services furnished under Medicare Part B are subject to the rules set forth in subpart E of part 409 of this chapter.

Subpart D—Comprehensive Outpatient Rehabilitation Facility (CORF) Services

§ 410.100 Included services.

Subject to the conditions and limitations set forth in §§ 410.102 and 410.105, CORF services means the following services furnished to an outpatient of the CORF by personnel that meet the qualifications set forth in § 485.70 of this chapter.

(a) *Physicians' services.* The following services of the facility physician constitute CORF services: consultation with and medical supervision of nonphysician staff, establishment and review of the plan of treatment, and other medical and facility administration activities. Those services are reimbursed on a reasonable cost basis under part 413 of this chapter. Diagnostic and therapeutic services furnished to an individual patient are not CORF physician's services. If covered, payment for these services would be made by the carrier on a reasonable charge basis subject to the provisions of subpart E of part 405 of this chapter.

(b) *Physical therapy services.* (1) These services include—

(i) Testing and measurement of the function or dysfunction of the neuromuscular, musculoskeletal, cardiovascular and respiratory systems; and.

(ii) Assessment and treatment related to dysfunction caused by illness or injury, and aimed at preventing or reducing disability or pain and restoring lost function.

(2) The establishment of a maintenance therapy program for an individual whose restoration potential has been reached is a physical therapy service; however, maintenance therapy itself is not covered as part of these services.

(c) *Occupational therapy services.* These services include—

(1) Teaching of compensatory techniques to permit an individual with a physical impairment or limitation to engage in daily activities.

(2) Evaluation of an individual's level of independent functioning.

(3) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; and

(4) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(d) *Speech-language pathology services.* These are services for the diagnosis and treatment of speech and language disorders that create difficulties in communication.

(e) *Respiratory therapy services.* (1) These are services for the assessment, diagnostic evaluation, treatment, management, and monitoring of patients with deficiencies or abnormalities of cardiopulmonary function.

(2) These services include—

(i) Application of techniques for support of oxygenation and ventilation of the patient and for pulmonary rehabilitation.

(ii) Therapeutic use and monitoring of gases, mists, and aerosols and related equipment;

(iii) Bronchial hygiene therapy;

(iv) Pulmonary rehabilitation techniques such as exercise conditioning, breathing retraining and patient education in the management of respiratory problems.

(v) Diagnostic tests to be evaluated by a physician, such as pulmonary function tests, spirometry and blood gas analysis; and

(vi) Periodic assessment of chronically ill patients and their need for respiratory therapy.

(f) *Prosthetic device services.* These services include—

(1) Prosthetic devices (excluding dental devices and renal dialysis machines), that replace all or part of an internal body organ or external body member (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning external body member or internal body organ; and

(2) Services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct the patient in its use.

(g) *Orthotic device services.* These services include—

(1) Orthopedic devices that support or align movable parts of the body, prevent or correct deformities, or improve functioning; and

(2) Services necessary to design the device, select the materials and components, measure, fit, and align the device, and instruct the patient in its use.

(h) *Social services.* These services include—

(1) Assessment of the social and emotional factors related to the individual's illness, need for care, response to treatment, and adjustment to care furnished by the facility;

(2) Casework services to assist in resolving social or emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment; and

(3) Assessment of the relationship of the individual's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from facility care.

(i) *Psychological services.* These services include—

(1) Assessment, diagnosis and treatment of an individual's mental and emotional functioning as it relates to the individual's rehabilitation;

(2) Psychological evaluations of the individual's response to and rate of progress under the treatment plan; and

(3) Assessment of those aspects of an individual's family and home situation that affect the individual's rehabilitation treatment.

(j) *Nursing care services.* These services include nursing services specified in the plan of treatment and any other nursing services necessary for the attainment of the rehabilitation goals.

(k) *Drugs and biologicals.* These are drugs and biologicals that are—

(1) Prescribed by a physician and administered by or under the supervision of a physician or a registered professional nurse; and

(2) Not excluded from Medicare Part B payment for reasons specified in §410.29.

(l) *Supplies, appliances, and equipment.* These include—

(1) Non-reusable supplies such as oxygen and bandages;

(2) Medical equipment and appliances; and

(3) Durable medical equipment of the type specified in § 410.38, (except renal dialysis systems) for use outside the CORF, whether purchased or rented.

(m) *Home environment evaluation.* This is a single home visit to evaluate the potential impact of the home situation on the rehabilitation goals.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987]

§ 410.102 Excluded services.

None of the services specified in § 410.100 is covered as a CORF service if the service—

(a) Would not be covered as an inpatient hospital service if furnished to a hospital inpatient;

(b) Is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. An example would be services furnished as part of a maintenance program involving repetitive activities that do not require the skilled services of nurses or therapists.

§ 410.105 Requirements for coverage of CORF services.

Services specified in § 410.100 and not excluded under § 410.102 are covered as CORF services if they are furnished by a participating CORF (that is, a CORF that meets the conditions of subpart B of part 485 of this chapter, and has in effect a provider agreement under part 489 of this chapter) and if the following requirements are met:

(a) *Referral and medical history.* The services must be furnished to an individual who is referred by a physician who certifies that the individual needs skilled rehabilitation services, and makes the following information available to the CORF before or at the time treatment is begun:

(1) The individual's significant medical history.

(2) Current medical findings.

(3) Diagnosis(es) and contraindications to any treatment modality.

(4) Rehabilitation goals, if determined.

(b) *When and where services are furnished.* (1) All services must be furnished while the individual is under the care of a physician.

(2) Except as provided in paragraph (b)(3) of this section, the services must be furnished on the premises of the CORF.

(3) *Exceptions.* (i) Physical therapy, occupational therapy, and speech pathology services may be furnished away from the premises of the CORF.

(ii) The single home visit specified in § 410.100(m) is also covered.

(c) *Plan of treatment.* (1) The services must be furnished under a written plan of treatment that—

(i) Is established and signed by a physician before treatment is begun; and

(ii) Prescribes the type, amount, frequency, and duration of the services to be furnished, and indicates the diagnosis and anticipated rehabilitation goals.

(2) The plan must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing the services.

(3) The reviewing physician must certify or recertify that the plan is being followed, the patient is making progress in attaining the rehabilitation goals, and the treatment is having no harmful effects on the patient.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8841, Mar. 1, 1991]

Subpart E—Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services

§ 410.110 Requirements for coverage of partial hospitalization services by CMHCs.

Medicare part B covers partial hospitalization services furnished by or under arrangements made by a CMHC if they are provided by a CMHC as defined in § 410.2 that has in effect a provider agreement under part 489 of this chapter and if the services are—

(a) Prescribed by a physician and furnished under the general supervision of a physician;

(b) Subject to certification by a physician in accordance with §424.24(e)(1) of this subchapter; and

(c) Furnished under a plan of treatment that meets the requirements of §424.24(e)(2) of this subchapter.

[59 FR 6577, Feb. 11, 1994]

Subpart F [Reserved]

Subpart G—Medical Nutrition Therapy

SOURCE: 66 FR 55331, Nov. 1, 2001, unless otherwise noted.

§410.130 Definitions.

For the purposes of this subpart, the following definitions apply:

Chronic renal insufficiency means the stage of renal disease associated with a reduction in renal function not severe enough to require dialysis or transplantation (glomerular filtration rate [GFR] 13–50 ml/min/1.73m^2).

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

Episode of care means services covered in a 12-month time period when coordinated with initial diabetes self-management training (DSMT) and one calendar year for each year thereafter, starting with the assessment and including all covered interventions based on referral(s) from a physician as specified in §410.132(c). The time period covered for gestational diabetes extends only until the pregnancy ends.

Medical nutrition therapy services means nutritional diagnostic, therapeutic, and counseling services provided by a registered dietitian or nutrition professional for the purpose of managing diabetes or a renal disease.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs such function or action (including a physician within the meaning of section of 1101(a)(7) of the Act).

Renal disease means chronic renal insufficiency, end-stage renal disease when dialysis is not received, or the medical condition of a beneficiary for 36 months after kidney transplant.

Treating physician means the primary care physician or specialist coordinating care for the beneficiary with diabetes or renal disease.

[66 FR 55331, Nov. 1, 2001, as amended at 68 FR 63261, Nov. 7, 2003]

§410.132 Medical nutrition therapy.

(a) *Conditions for coverage of MNT services*. Medicare Part B pays for MNT services provided by a registered dietitian or nutrition professional as defined in §410.134 when the beneficiary is referred for the service by the treating physician. Services covered consist of face-to-face nutritional assessments and interventions in accordance with nationally accepted dietary or nutritional protocols.

(b) *Limitations on coverage of MNT services*.

(1) MNT services based on a diagnosis of renal disease as described in this subpart are not covered for beneficiaries receiving maintenance dialysis for which payment is made under section 1881 of the Act.

(2) A beneficiary may only receive the maximum number of hours covered under the DSMT benefit for both DSMT and MNT during the initial DSMT training period unless additional hours are determined to be medically necessary under the national coverage determination process.

(3) In years when the beneficiary is eligible for MNT and follow-up DSMT, the beneficiary may only receive the maximum number of hours covered under MNT unless additional hours are determined to be medically necessary under the national coverage determination process.

(4) If a beneficiary has both diabetes and renal disease, the beneficiary may only receive the maximum number of hours covered under the renal MNT benefit in one episode of care unless he or she is receiving initial DSMT services, in which case the beneficiary would receive whichever is greater.

(5) An exception to the maximum number of hours in (b)(2), (3), and (4) of this section may be made when the treating physician determines that there is a change of diagnosis, medical condition, or treatment regimen related to diabetes or renal disease that requires a change in MNT during an episode of care.

(c) *Referrals*. Referral may only be made by the treating physician when the beneficiary has been diagnosed with diabetes or renal disease as defined in this subpart with documentation maintained by the referring physician in the beneficiary's medical record. Referrals must be made for each episode of care and any additional assessments or interventions required by a change of diagnosis, medical condition, or treatment regimen during an episode of care.

§ 410.134 Provider qualifications.

For Medicare Part B coverage of MNT, only a registered dietitian or nutrition professional may provide the services. ''Registered dietitian or nutrition professional'' means an individual who, on or after December 22, 2000:

(a) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.

(b) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.

(c) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a ''registered dietitian'' by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a) and (b) of this section.

(d) *Exceptions*.

(i) A dietitian or nutritionist licensed or certified in a State as of December 21, 2000 is not required to meet the requirements of (a) and (b) of this section.

(ii) A ''registered dietitian'' in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met the requirements of (a) and (b) of this section.

[66 55331, Nov. 1, 2001; 67 FR 20684, Apr. 26, 2002]

Subpart H—Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

SOURCE: 65 FR 83148, Dec. 29, 2000, unless otherwise noted.

§ 410.140 Definitions.

For purposes of this subpart, the following definitions apply:

ADA stands for the American Diabetes Association.

Approved entity means an individual, physician, or entity accredited by an approved organization as meeting one of the sets of quality standards described in § 410.144 and approved by CMS under § 410.141(e) to furnish training.

Deemed entity means an individual, physician, or entity accredited by an approved organization, but that has not yet been approved by CMS to furnish and receive Medicare payment for the training. Upon being approved by CMS under § 410.141(e) to furnish training, CMS refers to this entity as an ''approved entity''.

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

NSDSMEP stands for the National Standards for Diabetes Self Management Education Programs.

Organization means a national accreditation organization.

Rural means an area that meets one of the following conditions:

(1) Is not urbanized (as defined by the Bureau of the Census) and that is designated by the chief executive officer of the State, and certified by the Secretary, as an area with a shortage of personal health services.

(2) Is designated by the Secretary either as an area with a shortage of personal health services or as a health professional shortage area.

(3) Is designated by the Indian Health Service as a health service delivery area as defined in §36.15 of this title.

Training means outpatient diabetes self-management training.

[65 FR 83148, Dec. 29, 2000, as amended at 68 FR 63261, Nov. 7, 2003]

§410.141 Outpatient diabetes self-management training.

(a) *General rule*. Medicare Part B covers training defined in §410.140 if all of the conditions and requirements of this subpart are met.

(b) *Conditions for coverage*. The training must meet the following conditions:

(1) *Training orders*. Following an evaluation of the beneficiary's need for the training, it is ordered by the physician (or qualified nonphysician practitioner) (as defined in §410.32(a)) treating the beneficiary's diabetes.

(2) *Plan of care*. It is included in a comprehensive plan of care established by the physician (or qualified nonphysician practitioner) treating the beneficiary for diabetes that meets the following requirements:

(i) Describes the content, number of sessions, frequency, and duration of the training as written by the physician (or qualified nonphysician practitioner) treating the beneficiary.

(ii) Contains a statement specified by CMS and signed by the physician (or qualified nonphysician practitioner) managing the beneficiary's diabetic condition. By signing this statement, the physician (or qualified nonphysician practitioner) certifies that he or she is managing the beneficiary's diabetic condition and the training described in the plan of care is needed to ensure therapy compliance or to provide the beneficiary with the skills and knowledge to help manage the beneficiary's diabetes. The physician's (or qualified nonphysician practitioner's) statement must identify the beneficiary's specific medical conditions (described in paragraph (d) of this section) that the training will address.

(iii) Provides that any changes to the plan of care are signed by the physician (or qualified nonphysician practitioner) treating the beneficiary.

(iv) Is incorporated into the approved entity's medical record for the beneficiary and is made available, upon request, to CMS.

(3) *Reasonable and necessary*. It is reasonable and necessary for treating or monitoring the condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(c) Types and frequency of training—

(1) Initial training—

General rule. (i) Medicare Part B covers initial training that meets the following conditions:

(A) Is furnished to a beneficiary who has not previously received initial training under this benefit.

(B) Is furnished within a continuous 12-month period.

(C) Does not exceed a total of 10 hours.

(D) Except as permitted under paragraph (c)(1)(ii) of this section, 9 hours of the training are furnished in a group setting consisting of 2 to 20 individuals who need not all be Medicare beneficiaries.

(E) Is furnished in increments of no less than one-half hour.

(F) May include 1 hour of individual training for an assessment of the beneficiary's training needs.

(ii)

Exception. Medicare covers training on an individual basis for a Medicare beneficiary who meets any of the following conditions:

(A) No group session is available within 2 months of the date the training is ordered.

(B) The beneficiary's physician (or qualified nonphysician practitioner) documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions, such as severe vision, hearing, or language limitations that will hinder effective participation in a group training session.

(2)

Follow-up training. After receiving the initial training described in paragraph (c)(1) of this section, Medicare covers follow-up training that meets the following conditions:

(i) Consists of no more than 2 hours individual or group training for a beneficiary each year.

(ii) Group training consists of 2 to 20 individuals who need not all be Medicare beneficiaries.

(iii) Is furnished any time in a calendar year following the year in which the beneficiary completes the initial training.

(iv) Is furnished in increments of no less than one-half hour.

(v) The physician (or qualified nonphysician practitioner) treating the beneficiary must document, in the referral for training and the beneficiary's medical record, the specific medical condition (described in paragraph (d) of this section) that the follow-up training must address.

(d) *Beneficiaries who may be covered*. Medicare Part B covers outpatient diabetes self-management training for a beneficiary who has been diagnosed with diabetes.

(e) *Who may furnish services*. Training may be furnished by a physician, individual, or entity that meets the following conditions:

(1) Furnishes other services for which direct Medicare payment may be made.

(2) May properly receive Medicare payment under § 424.73 or § 424.80 of this chapter, which set forth prohibitions on assignment and reassignment of benefits.

(3) Submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS under § 410.142 to meet one of the sets of quality standards described in § 410.144.

(4) Provides documentation to CMS, as requested, including diabetes outcome measurements set forth at § 410.146.

[65 FR 83148, Dec. 29, 2000, as amended at 68 FR 63261, Nov. 7, 2003]

§ 410.142 CMS process for approving national accreditation organizations.

(a) *General rule*. CMS may approve and recognize a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals with diabetes to accredit entities to furnish training.

(b) *Required information and materials*. An organization requesting CMS's approval and recognition of its accreditation program must furnish to CMS the following information and materials:

(1) The requirements and quality standards that the organization uses to accredit entities to furnish training.

(2) If an organization does not use the CMS quality standards or the NSDSMEP quality standards described in § 410.144(a) or (b), a detailed comparison including a crosswalk between the organization's standards and the CMS quality standards described in § 410.144(a).

(3) Detailed information about the organization's accreditation process, including all of the following information:

(i) Frequency of accreditation.

(ii) Copies of accreditation forms, guidelines, and instructions to evaluators.

(iii) Descriptions of the following:

(A) The accreditation review process and the accreditation status decision making process.

(B) The procedures used to notify a deemed entity of deficiencies in its outpatient diabetes self-management training program and procedures to monitor the correction of those deficiencies.

(C) The procedures used to enforce compliance with the accreditation requirements and standards.

(4) Detailed information about the individuals who perform evaluations for the organization, including all of the following information:

(i) The education and experience requirements for the individuals who perform evaluations.

(ii) The content and frequency of continuing education furnished to the individuals who perform evaluations.

(iii) The process used to monitor the performance of individuals who perform evaluations.

(iv) The organization's policies and practices for participation in the accreditation process by an individual who is professionally or financially affiliated with the entity being evaluated.

(5) A description of the organization's data management and analysis system for its accreditation activities and decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.

(7) A description of the organization's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that will serve as a basis for accreditation if CMS approves the organization.

(9) A list of all of the approved entities currently accredited to furnish training and the type, category, and expiration date of the accreditation held by each of them.

(10) The name and address of each person with an ownership or control interest in the organization.

(11) Documentation that demonstrates its ability to furnish CMS with electronic data in CMS-compatible format.

(12) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities.

(13) A statement acknowledging that, as a condition for approval and recognition by CMS of its accreditation program, it agrees to comply with the requirements set forth in §§410.142 through 410.146.

(14) Additional information CMS requests to enable it to respond to the organization's request for CMS approval and recognition of its accreditation program to accredit entities to furnish training.

(c) *Onsite visit.* CMS may visit the prospective organization's offices to verify information in the organization's application, including, but not limited to, review of documents, and interviews with the organization's staff.

(d) *Notice and comment*—(1) *Proposed notice.* CMS publishes a proposed notice in the FEDERAL REGISTER announcing its intention to approve an organization's request for CMS approval and recognition of its accreditation program and the standards it uses to accredit entities to furnish training. The notice includes the following information:

(i) The basis for approving the organization.

(ii) A description of how the organization's accreditation program applies and enforces quality standards that have been determined by CMS to meet or exceed the CMS quality standards described in §410.144(a) or how the organization would use the NSDSMEP quality standards described in §410.144(b).

(iii) An opportunity for public comment.

(2) *Final notice.* (i) After considering public comments CMS receives on the proposed notice, it publishes a final notice in the FEDERAL REGISTER indicating whether it has approved an organization's request for CMS approval and recognition of its accreditation program and the standards it uses to accredit entities to furnish training.

(ii) If CMS approves the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(e) *Criteria CMS uses to approve national accreditation organizations.* In deciding to approve and recognize an organization's accreditation program to accredit entities to furnish training, CMS considers the following criteria:

(1) The organization uses and enforces quality standards that CMS has

determined meet or exceed the CMS quality standards described in § 410.144(a), or uses the NSDSMEP quality standards described in § 410.144(b).

(2) The organization meets the requirements for approved organizations in § 410.143.

(3) The organization is not owned or controlled by the entities it accredits, as defined in § 413.17(b)(2) or (b)(3), respectively, of this chapter.

(4) The organization does not accredit any entity it owns or controls.

(f) *Notice of CMS's decision.* CMS notifies the prospective organization in writing of its decision. The notice includes the following information:

(1) Statement of approval or denial.

(2) If approved, the expiration date of CMS's approval and recognition of the accreditation program.

(3) If denied, the rationale for the denial and the reconsideration and reapplication procedures.

(g) *Reconsideration of adverse decision.* An organization that has received CMS's notice of denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training may request reconsideration of CMS's decision in accordance with part 488 subpart D of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an organization that has received CMS's notice of denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training may submit a new request to CMS if it meets the following conditions:

(i) Has revised its accreditation program to correct the deficiencies CMS noted in its denial notice.

(ii) Demonstrates, through documentation, the use of one of the sets of quality standards described in § 410.144.

(iii) Resubmits the application in its entirety.

(2) For an organization that has requested reconsideration of CMS's denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training, CMS will not consider the organization's new request until all administrative proceedings on the previous request have been completed.

(i) *Withdrawal.* An organization requesting CMS approval and recognition of its accreditation program to accredit entities may withdraw its application at any time.

(j) *Applying for continued CMS approval.* At least 6 months before the expiration of CMS's approval and recognition of the organization's program, an organization must request from CMS continued approval and recognition.

§ 410.143 Requirements for approved accreditation organizations.

(a) *Ongoing responsibilities of an approved accreditation organization.* An organization approved and recognized by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in writing, on a monthly basis, all of the following:

(i) Copies of all accreditation decisions and any accreditation-related information that CMS may require (including corrective action plans and summaries of unmet quality standards described in § 410.144).

(ii) Notice of all complaints related to approved entities.

(iii) Within 30 days of taking remedial or adverse action (including revocation, withdrawal, or revision of an approved entity's deemed status) against an approved entity, information describing the remedial or adverse action and the circumstances that led to taking the action.

(iv) Notice of any proposed changes in its accreditation standards and requirements or evaluation process. If an organization implements changes without CMS approval (other than changes to the NSDSMEP quality standards described in § 410.144(b)), CMS may withdraw its approval and recognition of the organization's accreditation program.

(2) If an organization does not use the NSDSMEP quality standards described in § 410.144(b), and wishes to change its quality standards that CMS previously approved, the organization must submit its plan to alter its quality standards and include a crosswalk between the set of quality standards described

in §410.144 and the organization's revised standards. If an organization implements changes in its quality standards without CMS approval, CMS may withdraw its approval and recognition of the organization's accreditation program.

(3) If CMS notifies an organization that uses the CMS quality standards described in §410.144(a) that it has changed the CMS quality standards, the organization must meet the following requirements:

(i) Submit to CMS, within 30 days of CMS's notification of a change in the quality standards, its organization's plan to alter its quality standards to conform to the revised quality standards described in §410.144(a).

(ii) Implement the changes to its accreditation program by the implementation date specified in CMS's notification of the changes in the quality standards.

(b) *CMS oversight of approved national accreditation organizations.* CMS, or its agent, performs oversight activities to ensure that an approved organization and the entities the organization accredits continue to meet a set of quality standards described in §410.144. CMS (or its agent) uses the following procedures:

(1) Equivalency review. CMS compares the organization's standards and its application and enforcement of its standards to a set of quality standards (described in §410.144) and processes when any of the following conditions exist:

(i) CMS imposes new requirements or changes its process for approving and recognizing an organization.

(ii) Except for an organization that uses the NSDSMEP quality standards, the organization proposes to adopt new standards or changes its accreditation process.

(iii) The organization reapplies to CMS for continuation of its approval and recognition by CMS of its program to accredit entities to furnish training.

(2) Validation reviews. CMS validates an organization's accreditation process by conducting evaluations of approved entities accredited by the organization and comparing its results to the results of the organization's evaluation of the approved entities.

(3) Onsite inspections. CMS may conduct an onsite inspection of the organization's operations and offices to verify information and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing documentation of meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decision making process, and interviewing the organization's staff.

(4) Withdrawal of CMS approval and recognition—(i) CMS gives an organization written notice of CMS's intent to withdraw its approval and recognition of the organization's program to accredit entities if CMS determines through an equivalency review, validation review, onsite inspection, or CMS's daily experience with the organization that any of the following conditions exist:

(A) Except for those accrediting organizations using quality standards in §410.144(b), the quality standards that the organization applies and enforces do not meet or exceed the CMS quality standards described in §410.144(a).

(B) The organization has failed to meet the requirements for accreditation in §§410.142 through 410.144.

(ii) Request for reconsideration. An organization may request a reconsideration of CMS's decision to withdraw its approval and recognition of the organization in accordance with part 488, subpart D of this chapter.

§410.144 Quality standards for deemed entities.

An organization approved and recognized by CMS may accredit an entity to meet one of the following sets of quality standards:

(a) *CMS quality standards.* Standards prescribed by CMS, which include the following:

(1) Organizational structure. (i) Provides the educational resources to support the programs offered and the beneficiaries served, including adequate space, personnel, budget, instructional materials, confidentiality, privacy, and operational support.

(ii) Defines clearly and documents the organizational relationships, lines

of authority, staffing, job descriptions, and operational policies.

(iii) Maintains a written policy that affirms education as an integral component of diabetes care.

(iv) Includes in its operational policies, specific standards and procedures identifying the amount of collaborative, interactive, skill-based training methods and didactic training methods furnished to the beneficiary.

(v) Assesses the service area to define the target population in order to appropriately allocate personnel and resources.

(vi) Identifies in its operational policies, the minimal amount that each team member must be involved in the following:

(A) Development of training materials.

(B) Instruction of beneficiaries.

(2) Environment. Maintains a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of all patients and that meets all applicable fire protection and life safety codes.

(3) Program staff. (i) Requires a program coordinator who is responsible for program planning, implementation, and evaluation.

(ii) Requires nonphysician professional staff to obtain 12 hours of continuing diabetes education concerning educational principles and behavior change strategies every 2 years.

(4) Team approach. (i) Except as provided in paragraph (a)(4)(ii) of this section for a rural area, furnishes services using a multidisciplinary instructional team that meets the following requirements:

(A) The team includes at least a registered dietitian, as recognized under State law, and a certified diabetes educator (CDE), certified by a qualified organization that has registered with CMS, who have didactic experience and knowledge of diabetes clinical and educational issues. (If the team includes a registered nurse, an approved entity may delay implementation of the requirement for a CDE until February 27, 2004.)

(B) The team is qualified to teach the training content areas required in paragraph (a)(5) of this section.

(C) All appropriate team members must be present during the portion of the training for which they are responsible and must directly furnish the training within the scope of their practices.

(ii) In a rural area, an individual who is qualified as a registered dietitian and as a CDE that is currently certified by an organization approved by CMS (or until February 27, 2004 an individual who is qualified as a registered dietitian and as a registered nurse) may furnish training and is deemed to meet the multidisciplinary team requirement in paragraph (a)(4)(i) of this section.

(5) Training content. Offers training and is capable of meeting the needs of its patients on the following subjects:

(i) Diabetes overview/pathophysiology of diabetes.

(ii) Nutrition.

(iii) Exercise and activity.

(iv) Diabetes medications (including skills related to the self-administration of injectable drugs).

(v) Self-monitoring and use of the results.

(vi) Prevention, detection, and treatment of acute complications.

(vii) Prevention, detection, and treatment of chronic complications.

(viii) Foot, skin, and dental care.

(ix) Behavior change strategies, goal setting, risk factor reduction, and problem solving.

(x) Preconception care, pregnancy, and gestational diabetes.

(xi) Relationships among nutrition, exercise, medication, and blood glucose levels.

(xii) Stress and psychosocial adjustment.

(xiii) Family involvement and social support.

(xiv) Benefits, risks, and management options for improving glucose control.

(xv) Use of health care systems and community resources.

(6) Training methods. (i) Offers individual and group instruction for effective training.

(ii) Uses instructional methods and materials that are appropriate for the target population, and participants being served.

(iii) Uses primarily interactive, collaborative, skill-based training methods and maximizes the use of interactive training methods.

(7) Review of plan of care and goals. (i) Reviews each beneficiary's plan of care.

(ii) Develops and updates an individual assessment, in collaboration with each beneficiary, that includes relevant medical history, present health status, health service or resource utilization, risk factors, diabetes knowledge and skills, cultural influences, health beliefs and attitudes, health behaviors and goals, support systems, barriers to learning, and socioeconomic factors.

(iii) Based on the assessment, develops, in collaboration with each beneficiary, an individual education plan. Includes in the education plan, the goals for education, the periodic updates, the specific amount of interactive, collaborative, skill-based training methods and didactic training methods that have been and will be furnished.

(iv) Documents the results, including assessment, intervention, evaluation and follow-up in the beneficiary's medical record.

(v) Forwards a copy of the documentation in paragraph (a)(7)(ii) through (iv) of this section to the referring physician (or qualified nonphysician practitioner).

(vi) Periodically updates the beneficiary's referring physician (or qualified nonphysician practitioner) about the beneficiary's educational status.

(8) Educational intervention. Offers appropriate and timely educational intervention based on referral from the beneficiary's physician (or qualified nonphysician practitioner) and based on periodic reassessments of health status, knowledge, skills, attitudes, goals, and self-care behaviors.

(9) Performance measurement and quality improvement. Establishes and maintains an effective internal performance measurement and quality improvement program that focuses on maximizing outcomes by improving patient safety and quality of care. The program must meet the following requirements:

(i) Stresses health outcomes (for example, improved beneficiary diabetes control, beneficiary understanding, or beneficiary compliance) and provides for the collection, analysis, and reporting of data that permits measurement of performance outcomes, or other quality indicators.

(ii) Requires an entity to take the following actions:

(A) Evaluate itself on an annual basis as to its effectiveness in using performance measures.

(B) Improve its performance on at least one outcome or quality indicator each year.

(10) Quality improvement. Has an agreement with a QIO to participate in quality improvement projects defined by the QIO, or if a program elects not to participate in a QIO project, it must be able to demonstrate a level of achievement through a project of its own design that is comparable to or better than the achievement to be expected from participation in the QIO quality improvement project.

(b) *The National Standards for Diabetes Self-Management Education Programs.* The set of quality standards contained in the NSDSMEP or any NSDSMEP standards subsequently revised.

(c) *Standards of a national accreditation organization that represents individuals with diabetes.* Standards that meet or exceed the CMS quality standards described in paragraph (a) of this section that have been developed by a national organization (and approved by CMS) that is either a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals, including health care professionals and Medicare beneficiaries, with diabetes.

§410.145 Requirements for entities.

(a) *Deemed entities.* (1) Except as permitted in paragraph (a)(2) of this section, an entity may be deemed to meet a set of quality standards described in §410.144 if the following conditions are met:

(i) The entity has submitted necessary documentation and is fully accredited (and periodically reaccredited) by an organization approved by CMS under §410.142.

(ii) The entity is not accredited by an organization that owns or controls the entity.

(2) Before August 27, 2002 CMS may deem an entity to meet the NSDSMEP quality standards described in § 410.144(b), if the entity provides the Medicare contractor that will process its claims with a copy of a current certificate the entity received from the ADA that verifies the training program it furnishes meets the NSDSMEP quality standards described in § 410.144(b).

(b) *Approved entities.* An entity may be approved to furnish training if the entity meets the following conditions:

(1) Before submitting a claim for Medicare payment, forwards a copy of its certificate or proof of accreditation from an organization approved by CMS under § 410.142 indicating that the entity meets a set of quality standards described in § 410.144, or before August 27, 2002, submits documentation of its current ADA recognition status.

(2) Agrees to submit to evaluation (including onsite inspections) by CMS (or its agent) to validate its approved organization's accreditation process.

(3) Authorizes its approved organization to release to CMS a copy of its most recent accreditation evaluation, and any accreditation-related information that CMS may require.

(4) At a minimum, allows the QIO (under a contract with CMS) access to beneficiary or group training records.

(c) *Effective dates*—(1) *Deemed to meet quality standards.* Except as permitted in paragraph (c)(2) of this section, the date on which an entity is deemed to meet a set of quality standards described in § 410.144 is the later of one of the following dates:

(i) The date CMS approves and recognizes the accreditation organization to accredit entities to furnish training.

(ii) The date an organization accredits the entity to meet a set of quality standards described in § 410.144.

(2) *Approved to furnish training.* CMS covers the training furnished by an entity beginning on the later of one of the following dates:

(i) The date CMS approves the deemed entity as meeting the conditions for coverage in § 410.141(e).

(ii) The date the entity is deemed to meet a set of quality standards described in § 410.144.

(d) *Removal of approved status*—(1) *General rule.* CMS removes an entity's approved status for any of the following reasons:

(i) CMS determines, on the basis of its own evaluation or the results of the accreditation evaluation, that the entity does not meet a set of quality standards described in § 410.144.

(ii) CMS withdraws its approval of the organization that deemed the entity to meet a set of quality standards described in § 410.144.

(iii) The entity fails to meet the requirements of paragraphs (a) and (b) of this section.

(2) *Effective date.* The effective date of CMS's removal of an entity's approved status is 60 days after the date of CMS's notice to the entity.

§ 410.146 Diabetes outcome measurements.

(a) *Information collection.* An approved entity must collect and record in an organized systematic manner the following patient assessment information at least on a quarterly basis for a beneficiary who receives training under § 410.141:

(1) Medical information that includes the following:

(i) Duration of the diabetic condition.

(ii) Use of insulin or oral agents.

(iii) Height and weight by date.

(iv) Results and date of last lipid test.

(v) Results and date of last HbA1C.

(vi) Information on self-monitoring (frequency and results).

(vii) Blood pressure with the corresponding dates.

(viii) Date of the last eye exam.

(2) Other information that includes the following:

(i) Educational goals.

(ii) Assessment of educational needs.

(iii) Training goals.

(iv) Plan for a follow-up assessment of achievement of training goals between 6 months and 1 year after the beneficiary completes the training.

(v) Documentation of the training goals assessment.

(b) *Follow-up assessment information.* An approved entity may obtain information from the beneficiary's survey, primary care physician contact, and follow-up visits.

Subpart I—Payment of SMI Benefits

SOURCE: 51 FR 41339, Nov. 14, 1986, unless otherwise noted. Redesignated at 59 FR 6577, Feb. 11, 1994.

§410.150 To whom payment is made.

(a) *General rules.* (1) Any SMI enrollee is, subject to the conditions, limitations, and exclusions set forth in this part and in parts 405, 416 and 424 of this chapter, entitled to have payment made as specified in paragraph (b) of this section.

(2) The services specified in paragraphs (b)(5) through (b)(14) of this section must be furnished by a facility that has in effect a provider agreement or other appropriate agreement to participate in Medicare.

(b) *Specific rules.* Subject to the conditions set forth in paragraph (a) of this section, Medicare Part B pays as follows:

(1) To the individual, or to a physician or other supplier on the individual's behalf, for medical and other health services furnished by the physician or other supplier.

(2) To a nonparticipating hospital on the individual's behalf for emergency outpatient services furnished by the hospital, in accordance with subpart G of part 424 of this chapter.

(3) To the individual, for emergency outpatient services furnished by a nonparticipating hospital, in accordance with §424.53 of this chapter.

(4) To the individual, for physicians' services and ambulance services furnished outside the United States in accordance with §424.53 of this chapter.

(5) To a provider on the individual's behalf for medical and other health services furnished by the provider (or by others under arrangements made with them by the provider).

(6) To a home health agency on the individual's behalf for home health services furnished by the home health agency.

(7) To a clinic, rehabilitation agency, or public health agency on the individual's behalf for outpatient physical therapy or speech pathology services furnished by the clinic or agency (or by others under arrangements made with them by the clinic or agency).

(8) To a rural health clinic or Federally qualified health center on the individual's behalf for rural health clinic or Federally qualified health center services furnished by the rural health clinic or Federally qualified health center, respectively.

(9) To an ambulatory surgical center (ASC) on the individual's behalf for covered ambulatory surgical center facility services that are furnished in connection with surgical procedures performed in an ASC, as provided in part 416 of this chapter.

(10) To a comprehensive outpatient rehabilitation facility (CORF) on the individual's behalf for comprehensive outpatient rehabilitation facility services furnished by the CORF.

(11) To a renal dialysis facility, on the individual's behalf, for institutional or home dialysis services, supplies, and equipment furnished by the facility.

(12) To a critical access hospital (CAH) on the individual's behalf for outpatient CAH services furnished by the CAH.

(13) To a community mental health center (CMHC) on the individual's behalf, for partial hospitalization services furnished by the CMHC (or by others under arrangements made with them by the CMHC).

(14) To an SNF for services (other than those described in §411.15(p)(2) of this chapter) that it furnishes to a resident (as defined in §411.15(p)(3) of this chapter) of the SNF who is not in a covered Part A stay.

(15) To the qualified employer of a physician assistant for professional services furnished by the physician assistant and for services and supplies furnished incident to his or her services. Payment is made to the employer of a physician assistant regardless of whether the physician assistant furnishes services under a W–2, employer-employee employment relationship, or whether the physician assistant is an independent contractor who receives a

1099 reflecting the relationship. Both types of relationships must conform to the appropriate guidelines provided by the Internal Revenue Service. A qualified employer is not a group of physician assistants that incorporate to bill for their services. Payment is made only if no facility or other provider charges or is paid any amount for services furnished by a physician assistant.

(16) To a nurse practitioner or clinical nurse specialist for professional services furnished by a nurse practitioner or clinical nurse specialist in all settings in both rural and nonrural areas and for services and supplies furnished incident to those services. Payment is made only if no facility or other provider charges, or is paid, any amount for the furnishing of the professional services of the nurse practitioner or clinical nurse specialist.

(17) To a clinical psychologist on the individual's behalf for clinical psychologist services and for services and supplies furnished as an incident to his or her services.

(18) To a clinical social worker on the individual's behalf for clinical social worker services.

(19) To a participating HHA, for home health services (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 24981, June 12, 1992; 58 FR 30668, May 26, 1993; 59 FR 6577, Feb. 11, 1994; 63 FR 20129, Apr. 23, 1998; 63 FR 26308, May 12, 1998; 63 FR 58909, Nov. 2, 1998; 65 FR 41211, July 3, 2000; 66 FR 39599, July 31, 2001]

§ 410.152 Amounts of payment.

(a) *General provisions*—(1) *Exclusion from incurred expenses*. As used in this section, ''incurred expenses'' are expenses incurred by an individual, during his or her coverage period, for covered Part B services, excluding the following:

(i) Expenses incurred for services for which the beneficiary is entitled to have payment made under Medicare Part A or would be so entitled except for the application of the Part A deductible and coinsurance requirements.

(ii) Expenses incurred in meeting the Part B blood deductible (§ 410.161).

(iii) In the case of services payable under a formula that takes into account reasonable charges, reasonable costs, customary charges, customary (insofar as reasonable) charges, charges related to reasonable costs, fair compensation, a pre-treatment prospective payment rate, or a standard overhead amount, or any combination of two or more of these factors, expenses in excess of any factor taken into account under that formula.

(iv) Expenses in excess of the outpatient mental health treatment limitation described in § 410.155.

(v) In the case of expenses incurred for outpatient physical therapy services including speech-language pathology services, the expenses excluded are from the incurred expenses under § 410.60(e). In the case of expenses incurred for outpatient occupational therapy including speech-language pathology services, the expenses excluded are from the incurred expenses under § 410.59(e).

(2) *Other applicable provisions*. Medicare Part B pays for incurred expenses the amounts specified in paragraphs (b) through (k) of this section, subject to the following:

(i) The principles and procedures for determining reasonable costs and reasonable charges and the conditions for Medicare payment, as set forth in parts 405 (subparts E and X), 413, and 424 of this chapter.

(ii) The Part B annual deductible (§ 410.160).

(iii) The special rules for payment to health maintenance organizations (HMOs), health care prepayment plans (HCPPs), and competitive medical plans (CMPs) that are set forth in part 417 of this chapter. (A prepayment organization that does not qualify as an HMO, CMP, or HCPP is paid in accordance with paragraph (b)(4) of this section.)

(b) *Basic rules for payment*. Except as specified in paragraphs (c) through (h)

of this section, Medicare Part B pays the following amounts:

(1) For services furnished by, or under arrangements made by, a provider other than a nominal charge provider, whichever of the following is less:

(i) 80 percent of the reasonable cost of the services.

(ii) The reasonable cost of, or the customary charges for, the services, whichever is less, minus 20 percent of the customary (insofar as reasonable) charges for the services.

(2) For services furnished by, or under arrangements made by, a nominal charge provider, 80 percent of fair compensation.

(3) For emergency outpatient hospital services furnished by a nonparticipating hospital that is eligible to receive payment for those services under subpart G of part 424 of this chapter, the amount specified in paragraph (b)(1) of this section.

(4) For services furnished by a person or an entity other than those specified in paragraphs (b)(1) through (b)(3) of this section, 80 percent of the reasonable charges or 80 percent of the payment amount computed on any other payment basis for the services.

(c) *Amount of payment: Home health services other than durable medical equipment (DME).* For home health services other than DME furnished by, or under arrangements made by, a participating HHA, Medicare Part B pays the following amounts:

(1) For services furnished by an HHA that is a nominal charge provider, 100 percent of fair compensation.

(2) For services furnished by an HHA that is not a nominal charge provider, the lesser of the reasonable cost of the services and the customary charges for the services.

(d) *Amount of payment: DME furnished as a home health service.*

(1) *Basic rule.* Except as specified in paragraph (d)(2) of this section—

(i) For DME furnished by an HHA that is a nominal charge provider, Medicare Part B pays 80 percent of fair compensation.

(ii) For DME furnished by an HHA that is not a nominal charge provider, Medicare Part B pays the lesser of the following:

(A) 80 percent of the reasonable cost of the service.

(B) The reasonable cost of, or the customary charge for, the service, whichever is less, minus 20 percent of the customary (insofar as reasonable) charge for the service.

(2) *Exception.* If the DME is used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for new equipment—

(i) For used DME furnished by an HHA that is a nominal charge provider, Medicare Part B pays 100 percent of fair compensation.

(ii) For used DME furnished by an HHA that is not a nominal charge provider, Medicare Part B pays 100 percent of the reasonable cost of, or the customary charge for, the services, whichever is less.

(e) *Amount of payment: Renal dialysis services, supplies, and equipment.* Effective for services furnished on or after August 1, 1983, Medicare Part B pays for the institutional dialysis services specified in §409.250 and the home dialysis services, supplies, and equipment specified in §409.252, as follows:

(1) Except as provided in paragraph (d)(2) of this section, 80 percent of the per treatment prospective reimbursement rate established under §413.170 of this chapter, for outpatient maintenance dialysis furnished by ESRD facilities approved in accordance with subpart U of part 405 of this chapter.

(2) *Exception.* If a home dialysis patient elects to obtain home dialysis supplies or equipment (or both) from a party other than an approved ESRD facility, payment is in accordance with paragraph (b)(4) of this section.

(f) *Amount of payment: Rural health clinic and Federally qualified health center services.* Medicare Part B pays, for services by a participating independent rural health clinic or Federally qualified health center, 80 percent of the costs determined under subpart X of part 405 of this chapter, to the extent those costs are reasonable and related to the cost of furnishing rural health clinic or Federally qualified health center services or reasonable on the basis of other tests specified by CMS.

(g) *Amount of payment: Used durable medical equipment furnished by otherthan*

an HHA. Medicare Part B pays the following amounts for used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for comparable new equipment:

(1) For used DME furnished by, or under arrangements made by, a nominal charge provider, 100 percent of fair compensation.

(2) For used DME furnished by or under arrangements made by a provider that is not a nominal charge provider, 100 percent of the reasonable cost of the service or the customary charge for the service, whichever is less.

(3) For used DME furnished by other than a provider, 100 percent of the reasonable charge.

(h) *Amount of payment: Pneumococcal vaccine*. Medicare Part B pays for pneumococcal vaccine and its administration as follows:

(1) For services furnished by a nominal charge provider, 100 percent of fair compensation.

(2) For services furnished by a provider that is not a nominal charge provider, the reasonable cost of the services or the customary charge for the service, whichever is less.

(3) For services furnished by other than a provider, a rural health clinic or a Federally qualified health center, 100 percent of the reasonable charge.

(4) For services furnished by a rural health clinic or a Federally qualified health center, 100 percent of the reasonable cost.

(i) *Amount of payment: ASC facility services*. For ASC facility services that are furnished in connection with the surgical procedures specified in part 416 of this chapter, Medicare Part B pays 80 percent of a standard overhead amount, as specified in § 416.120(c) of this chapter.[1]

(j) *Amount of payment: services of Federally funded health facilities prior to October 1, 1991*. Medicare Part B pays 80 percent of charges related to the reasonable costs that a Federally funded health facility incurs in furnishing the services. See § 411.8(b)(6) of this chapter.

(k) *Amount of payment: Outpatient CAH services*. (1) Payment for CAH outpatient services is the reasonable cost of the CAH in providing these services, as determined in accordance with section 1861(v)(1)(A) of the Act, with § 413.70(b) and (c) of this chapter, and with the applicable principles of cost reimbursement in part 413 and in part 415 of this chapter.

(2) Payment for CAH outpatient services is subject to the applicable Medicare Part B deductible and coinsurance amounts, except as described in § 413.70(b)(2)(iii) of this chapter, with Part B coinsurance being calculated as 20 percent of the customary (insofar as reasonable) charges of the CAH for the services.

(l) *Amount of payment: Flu vaccine*. Medicare Part B pays 100 percent of the Medicare allowed charge.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987, as amended at 53 FR 6648, Mar. 2, 1988; 56 FR 2138, Jan. 22, 1991; 56 FR 8841, Mar. 1, 1991; 57 FR 24981, June 12, 1992; 58 FR 30668, May 26, 1993; 59 FR 63462, Dec. 8, 1994; 62 FR 46025, Aug. 29, 1997; 63 FR 20129, Apr. 23, 1998; 63 FR 26357, May 12, 1998; 63 FR 35066, June 26, 1998; 63 FR 58910, Nov. 2, 1998; 65 FR 47047, 47105, Aug. 1, 2000; 66 FR 32192, June 13, 2001]

§ 410.155 Outpatient mental health treatment limitation.

(a) *Limitation*. Only 62½ percent of the expenses incurred for services subject to the limit as specified in paragraph (b) of this section are considered incurred expenses under Medicare Part B when determining the amount of payment and deductible under §§ 410.152 and 410.160, respectively.

(b) *Application of the limitation*—(1) *Services subject to the limitation*. Except as specified in paragraph (b)(2) of this section, the following services are subject to the limitation if they are furnished in connection with the treatment of a mental, psychoneurotic, or personality disorder (that is, any condition identified by a diagnosis code within the range of 290 through 319) and are furnished to an individual who is not an inpatient of a hospital:

(i) Services furnished by physicians and other practitioners, whether furnished directly or as an incident to those practitioners' services.

[1] For services furnished before July 1, 1987, Medicare Part B paid 100 percent of the standard amount.

(ii) Services provided by a CORF.

(2) *Services not subject to the limitation.* Services not subject to the limitation include the following:

(i) Services furnished to a hospital inpatient.

(ii) Brief office visits for the sole purpose of monitoring or changing drug prescriptions used in the treatment of mental, psychoneurotic, or personality disorders.

(iii) Partial hospitalization services not directly provided by a physician.

(iv) Diagnostic services, such as psychological testing, that are performed to establish a diagnosis.

(v) Medical management, as opposed to psychotherapy, furnished to a patient diagnosed with Alzheimer's disease or a related disorder.

(c) *Examples.* (1) A clinical psychologist submitted a claim for $200 for outpatient treatment of a beneficiary's mental disorder. The Medicare approved amount was $180. Since clinical psychologists must accept assignment, the beneficiary is not liable for the $20 in excess charges. The beneficiary previously satisfied the $100 annual Part B deductible. The limitation reduces the amount of incurred expenses to 62½ percent of the approved amount. After subtracting any unmet deductible, Medicare pays 80 percent of the remaining incurred expenses. Medicare payment and beneficiary liability are computed as follows:

1. Actual charges	$200.00
2. Medicare approved amount	180.00
3. Medicare incurred expenses (0.625 × line 2)	112.50
4. Unmet deductible	0.00
5. Remainder after subtracting deductible (line 3 minus line 4)	112.50
6. Medicare payment (0.80 × line 5)	90.00
7. Beneficiary liability (line 2 minus line 6)	90.00

(2) A clinical social worker submitted a claim for $135 for outpatient treatment of a beneficiary's mental disorder. The Medicare approved amount was $120. Since clinical social workers must accept assignment, the beneficiary is not liable for the $15 in excess charges. The beneficiary previously satisfied $70 of the $100 annual Part B deductible, leaving $30 unmet.

1. Actual charges	$135.00
2. Medicare approved amount	120.00
3. Medicare incurred expenses (0.625 × line 2)	75.00
4. Unmet deductible	30.00
5. Remainder after subtracting deductible (line 3 minus line 4)	45.00
6. Medicare payment (0.80 × line 5)	36.00
7. Beneficiary liability (line 2 minus line 6)	84.00

(3) A physician who did not accept assignment submitted a claim for $780 for services in connection with the treatment of a mental disorder that did not require inpatient hospitalization. The Medicare approved amount was $750. Because the physician did not accept assignment, the beneficiary is liable for the $30 in excess charges. The beneficiary had not satisfied any of the $100 Part B annual deductible.

1. Actual charges	$780.00
2. Medicare approved amount	750.00
3. Medicare incurred expenses (0.625 × line 2)	468.75
4. Unmet deductible	100.00
5. Remainder after subtracting deductible (line 3 minus line 4)	368.75
6. Medicare payment (0.80 × line 5)	295.00
7. Beneficiary liability (line 1 minus line 6)	485.00

(4) A beneficiary's only Part B expenses during 1995 were for a physician's services in connection with the treatment of a mental disorder that initially required inpatient hospitalization. The remaining services were furnished on an outpatient basis. The beneficiary had not satisfied any of the $100 annual Part B deductible in 1995. The physician, who accepted assignment, submitted a claim for $780. The Medicare-approved amount was $750. The beneficiary incurred $350 of the approved amount while a hospital inpatient and incurred the remaining $400 of the approved amount for outpatient services. Only $400 of the approved amount is subject to the 62½ percent limitation because the statutory limitation does not apply to services furnished to hospital inpatients.

1. Actual charges	$780.00
2. Medicare approved amount	$750.00
2A. Inpatient portion	$350
2B. Outpatient portion	$400
3. Medicare incurred expenses	$600.00
3A. Inpatient portion	$350
3B. Outpatient portion (0.625 × line 2B)	$250
4. Unmet deductible	$100.00
5. Remainder after subtracting deductible (line 3 minus line 4)	$500.00
6. Medicare payment (0.80 × line 5)	$400.00
7. Beneficiary liability (line 2 minus line 6)	$350.00

[63 FR 20129, Apr. 23, 1998]

§ 410.160 Part B annual deductible.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, incurred expenses (as defined in § 410.152) are subject to, and count toward meeting the annual deductible.

(b) *Exceptions.* Expenses incurred for the following services are not subject to the Part B annual deductible and do not count toward meeting that deductible:

(1) Home health services.

(2) Pneumococcal vaccines and their administration.

(3) Federally qualified health center services.

(4) ASC facility services furnished before July 1987 and physician services furnished before April 1988 that met the requirements for payment of 100 percent of the reasonable charges.

(5) Screening mammography services as described in § 410.34 (c) and (d).

(6) Screening pelvic examinations as described in § 410.56.

(c) *Application of the Part B annual deductible.* (1) Before payment is made under § 410.152, an individual's incurred expenses for the calendar year are reduced by the Part B annual deductible.

(2) The Part B annual deductible is applied to incurred expenses in the order in which claims for those expenses are processed by the Medicare program.

(3) Only one Part B annual deductible may be imposed for any calendar year and it may be met by any combination of expenses incurred in that year.

(d) *Special rule for services reimbursable on a formula basis.* (1) In applying the formula that takes into account reasonable costs, customary charges, and customary (insofar as reasonable) charges, and is used to determine payment for services furnished by a provider that is not a nominal charge provider, the Medicare intermediary takes the following steps:

(i) Reduces the customary charges for the services by an amount equal to any unmet portion of the deductible for the calendar year, in accordance with paragraph (b) of this section. (The amount of this reduction is considered to be the amount of the deductible that is met on the basis of the services to which it is applied.)

(ii) Determines 20 percent of any remaining portion of the customary (insofar as reasonable) charge.

(iii) Determines the lesser of the reasonable cost of the services and the customary charges for the services.

(iv) Reduces the amount determined under paragraph (c)(1)(iii) of this section by the sum of the reduction made under paragraph (c)(1)(i) of this section and the amount determined under parargaph (c)(1)(ii) of this section.

(v) Reduces the reasonable cost of the services by the amount of the reduction made under paragraph (c)(1)(i) of this section and multiplies the result by 80 percent.

(2) In accordance with § 410.152(b)(1), the amount payable is the amount determined under paragraph (c)(1)(iv) of this section, or the amount determined under paragraph (c)(1)(v) of this section, whichever is less.

(e) *Special rule for services of an independent rural health clinic.* Application of the Part B annual deductible to rural health clinic services is in accordance with § 405.2425(b)(2) of this chapter.

(f) *Amount of the Part B annual deductible.* (1) Beginning with expenses for services furnished during calendar year 2006, and for all succeeding years, the annual deductible is the previous year's deductible plus the annual percentage increase in the monthly actuarial rate for Medicare enrollees age 65 and over, rounded to the nearest dollar.

(2) For 2005, the deductible is $110.

(3) From 1991 through 2004, the deductible was $100.

(4) From 1982 through 1990, the deductible was $75.

(5) From 1973 through 1981, the deductible was $60.

(6) From 1966 through 1972, the deductible was $50.

(g) *Carryover of Part B annual deductible.* For calendar years before 1982, the Part B annual deductible was reduced by the amount of expenses incurred during the last quarter of the preceding year that was applied to meet the deductible for that preceding year. *Example:* If $20 of expenses incurred in November 1980 was used to meet the 1980 deductible, the 1981 deductible was reduced to $40 ($60–$20).

(h) *Examples of application of the annual deductible.* (1) Mr. A submitted claims for the following expenses incurred during 1982: $20 for services furnished in March by physician X; $30 for services furnished in April by physician Y; $50 for services furnished in June by physician Z, for a total of $100. The carrier determined that the charges as submitted were the reasonable charges. The first $75 of expenses for which claims were processed is applied to meet the $75 deductible for that year. Medicare Part B pays 80 percent of the remaining $25, or $20.

(2) Mr. B submitted a claim that included a $25 charge by a doctor for an examination to prescribe a hearing aid and an $80 charge for office surgery. This was the first claim relating to Mr. B's medical expenses processed in the calendar year. The carrier disallowed the $25 charge because the type of examination is not covered by Medicare. The carrier reduced the $80 surgery charge to a reasonable charge of $40. Only the $40 reasonable charge for covered services will count toward meeting Mr. B's deductible. Since the remainder of the surgery charge constitutes and excess over the reasonable charge, it cannot be applied to satisfy Mr. B's deductible.

(3) Mr. C became entitled to Medicare Part B benefits on July 1, 1982. He incurred expenses of $200 in July, August, and September. The carrier determined that the changes as submitted were reasonable. Even though Mr. C was entitled to benefits for only half the year, he must meet the full $75 deductible. Thus, $75 of this expense constitutes Mr. C's deductible. Medicare would pay $100, which is 80 percent of the remaining $125.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8842 and 8852, Mar. 1, 1991; 57 FR 24981, June 12, 1992; 62 FR 59101, Oct. 31, 1997; 69 FR 66423, Nov. 15, 2004]

§410.161 Part B blood deductible.

(a) *General rules.* (1) As used in this section, *packed red cells* means the red blood cells that remain after plasma is separated from whole blood.

(2) A unit of packed red cells is treated as the equivalent of a pint of whole blood, which in this section is referred to as a unit of whole blood.

(3) Medicare does not pay for the first 3 units of whole blood or units of packed red cells that are furnished under Part A or Part B in a calendar year. The Part B blood deductible is reduced to the extent that a blood deductible has been applied under Part A.

(4) The blood deductible does not apply to other blood components such as platelets, fibrinogen, plasma, gamma globulin and serum albumin, or to the costs of processing, storing, and administering blood.

(5) The blood deductible is in addition to the Part B annual deductible specified in §410.160.

(b) *Beneficiary's responsibility for the first 3 units of blood.* (1) The beneficiary is responsible for the first three units of whole blood or packed red cells received during a calendar year.

(2) If the blood is furnished by a hospital or CAH, the rules set forth in §409.87 (b), (c), and (d) of this chapter apply.

(3) If the blood is furnished by a physician, clinic, or other supplier that has accepted assignment of Medicare benefits, or claims payment under §424.64 of this chapter because the beneficiary died without assigning benefits, the supplier may charge the beneficiary the reasonable charge for the first 3 units, to the extent that those units are not replaced.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 56 FR 8852, Mar. 1, 1991; 58 FR 30668, May 26, 1993]

§410.163 Payment for services furnished to kidney donors.

Notwithstanding any other provisions of this chapter, there are no deductible or coinsurance requirements with respect to services furnished to an individual who donates a kidney for transplant surgery.

§410.165 Payment for rural health clinic services and ambulatory surgical center services: Conditions.

(a) Medicare Part B pays for covered rural health clinic and Federally qualified health center services if—

(1) The services are furnished in accordance with the requirements of subpart X of part 405 of this chapter and subpart A of part 491 of this chapter; and

(2) The clinic or center files a written request for payment on the form and in the manner prescribed by CMS.

(b) Medicare Part B pays for covered ambulatory surgical center (ASC) services if—

(1) The services are furnished in accordance with the requirements of part 416 of this chapter; and

(2) The ASC files a written request for payment on the form and in the manner prescribed by CMS.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 24981, June 12, 1992]

§ 410.170 Payment for home health services, for medical and other health services furnished by a provider or an approved ESRD facility, and for comprehensive outpatient rehabilitation facility (CORF) services: Conditions.

Payment under Medicare Part B, for home health services, for medical and other health services, or for CORF services, may be made to the provider or facility only if the following conditions are met:

(a) *Request for payment.* A written request for payment is filed by or on behalf of the individual to whom the services were furnished.

(b) *Physician certification.* (1) For home health services, a physician provides certification and recertification in accordance with § 424.22 of this chapter.

(2) For medical and other health services, a physician provides certification and recertification in accordance with § 424.24 of this chapter.

(3) For CORF services, a physician provides certification and recertification in accordance with § 424.27 of this chapter.

(c) In the case of home dialysis support services described in § 410.52, the services are furnished in accordance with a written plan prepared and periodically reviewed by a team that includes the patient's physician and other professionals familiar with the patient's condition as required by § 405.2137(b)(3) of this chapter.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.172 Payment for partial hospitalization services in CMHCs: Conditions.

Medicare Part B pays for partial hospitalization services furnished in a CMHC on behalf of an individual only if the following conditions are met:

(a) The CMHC files a written request for payment on the CMS form 1450 and in the manner prescribed by CMS; and

(b) The services are furnished in accordance with the requirements described in § 410.110.

[59 FR 6578, Feb. 11, 1994]

§ 410.175 Alien absent from the United States.

(a) Medicare does not pay Part B benefits for services furnished to an individual who is not a citizen or a national of the United States if those services are furnished in any month for which the individual is not paid monthly social security cash benefits (or would not be paid if he or she were entitled to those benefits) because he or she has been outside the United States continuously for 6 full calendar months.

(b) Payment of benefits resumes with services furnished during the first full calendar month the alien is back in the United States.

[53 FR 6634, Mar. 2, 1988]

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

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AUTHORITY: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395 w–101 through 1395w–152, and 1395hh).

SOURCE: 54 FR 41734, Oct. 11, 1989, unless otherwise noted.

Subpart A—General Exclusions and Exclusion of Particular Services

§ 411.1 Basis and scope.

(a) *Statutory basis.* Sections 1814(a) and 1835(a) of the Act require that a physician certify or recertify a patient's need for home health services but, in general, prohibit a physician from certifying or recertifying the need for services if the services will be furnished by an HHA in which the physician has a significant ownership interest, or with which the physician has a significant financial or contractual relationship. Sections 1814(c), 1835(d), and 1862 of the Act exclude from Medicare payment certain specified services. The Act provides special rules for payment of services furnished by the following: Federal providers or agencies (sections 1814(c) and 1835(d)); hospitals and physicians outside of the U.S. (sections 1814(f) and 1862(a)(4)); and hospitals and SNFs of the Indian Health Service (section 1880 of the Act). Section 1877 of the Act sets forth limitations on referrals and payment for designated health services furnished by entities with which the referring physician (or an immediate family member of the referring physician) has a financial relationship.

(b) *Scope.* This subpart identifies:

(1) The particular types of services that are excluded;

(2) The circumstances under which Medicare denies payment for certain services that are usually covered; and

(3) The circumstances under which Medicare pays for services usually excluded from payment.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 41978, Aug. 14, 1995; 60 FR 45361, Aug. 31, 1995; 66 FR 952, Jan. 4, 2001]

§411.2 Conclusive effect of QIO determinations on payment of claims.

If a utilization and quality control quality improvement organization (QIO) has assumed review responsibility, in accordance with part 466 of this chapter, for services furnished to Medicare beneficiaries, Medicare payment is not made for those services unless the conditions of subpart C of part 466 of this chapter are met.

§411.4 Services for which neither the beneficiary nor any other person is legally obligated to pay.

(a) *General rule.* Except as provided in §411.8(b) (for services paid by a governmental entity), Medicare does not pay for a service if—

(1) The beneficiary has no legal obligation to pay for the service; and

(2) No other person or organization (such as a prepayment plan of which the beneficiary is a member) has a legal obligation to provide or pay for that service.

(b) *Special conditions for services furnished to individuals in custody of penal authorities.* Payment may be made for services furnished to individuals or groups of individuals who are in the custody of the police or other penal authorities or in the custody of a government agency under a penal statute only if the following conditions are met:

(1) State or local law requires those individuals or groups of individuals to repay the cost of medical services they receive while in custody.

(2) The State or local government entity enforces the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts.

§411.6 Services furnished by a Federal provider of services or other Federal agency.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, Medicare does not pay for services furnished by a Federal provider of services or other Federal agency.

(b) *Exceptions.* Payment may be made—

(1) For emergency hospital services, if the conditions of §424.103 of this chapter are met;

(2) For services furnished by a participating Federal provider which CMS has determined is providing services to the public generally as a community institution or agency;

(3) For services furnished by participating hospitals and SNFs of the Indian Health Service; and

(4) For services furnished under arrangements (as defined in §409.3 of this chapter) made by a participating hospital.

§411.7 Services that must be furnished at public expense under a Federal law or Federal Government contract.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, payment may not be made for services that any provider or supplier is obligated to furnish at public expense, in accordance with a law of, or a contract with, the United States.

(b) *Exception.* Payment may be made for services that a hospital or SNF of the Indian Health Service is obligated to furnish at public expense.

§411.8 Services paid for by a Government entity.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, Medicare does not pay for services that are paid for directly or indirectly by a government entity.

(b) *Exceptions.* Payment may be made for the following:

(1) Services furnished under a health insurance plan established for employees of the government entity.

(2) Services furnished under a title of the Social Security Act other than title XVIII.

(3) Services furnished in or by a participating general or special hospital that—

(i) Is operated by a State or local government agency; and

(ii) Serves the general community.

(4) Services furnished in a hospital or elsewhere, as a means of controlling infectious diseases or because the individual is medically indigent.

(5) Services furnished by a participating hospital or SNF of the Indian Health Service.

(6) Services furnished by a public or private health facility that—

(i) Is not a Federal provider or other facility operated by a Federal agency;

(ii) Receives U.S. government funds under a Federal program that provides support to facilities that furnish health care services;

(iii) Customarily seeks payment for services not covered under Medicare from all available sources, including private insurance and patients' cash resources; and

(iv) Limits the amounts it collects or seeks to collect from a Medicare Part B beneficiary and others on the beneficiary's behalf to:

(A) Any unmet deductible applied to the charges related to the reasonable costs that the facility incurs in providing the covered services;

(B) Twenty percent of the remainder of those charges;

(C) The charges for noncovered services.

(7) Rural health clinic services that meet the requirements set forth in part 491 of this chapter.

[54 FR 41734, Oct. 11, 1989, as amended at 56 FR 2139, Jan. 22, 1991]

§ 411.9 Services furnished outside the United States.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, Medicare does not pay for services furnished outside the United States. For purposes of this paragraph (a), the following rules apply:

(1) The United States includes the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, The Northern Mariana Islands, and for purposes of services rendered on board ship, the territorial waters adjoining the land areas of the United States.

(2) Services furnished on board ship are considered to have been furnished in United States territorial waters if they were furnished while the ship was in a port of one of the jurisdictions listed in paragraph (a)(1) of this section, or within 6 hours before arrival at, or 6 hours after departure from, such a port.

(3) A hospital that is not physically situated in one of the jurisdictions listed in paragraph (a)(1) of this section is considered to be outside the United States, even if it is owned or operated by the United States Government.

(b) *Exception.* Under the circumstances specified in subpart H of part 424 of this chapter, payment may be made for covered inpatient services furnished in a foreign hospital and, on the basis of an itemized bill, for covered physicians' services and ambulance service furnished in connection with those inpatient services, but only for the period during which the inpatient hospital services are furnished.

§ 411.10 Services required as a result of war.

Medicare does not pay for services that are required as a result of war, or an act of war, that occurs after the effective date of a beneficiary's current coverage for hospital insurance benefits or supplementary medical insurance benefits.

§ 411.12 Charges imposed by an immediate relative or member of the beneficiary's household.

(a) *Basic rule.* Medicare does not pay for services usually covered under Medicare if the charges for those services are imposed by—

(1) An immediate relative of the beneficiary; or

(2) A member of the beneficiary's household.

(b) *Definitions.* As used in this section—

Immediate relative means any of the following:

(1) Husband or wife.

(2) Natural or adoptive parent, child, or sibling.

(3) Stepparent, stepchild, stepbrother, or stepsister.

(4) Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law.

(5) Grandparent or grandchild.

(6) Spouse of grandparent or grandchild.

Member of the household means any person sharing a common abode as part of a single family unit, including domestic employees and others who live together as part of a family unit, but not including a mere roomer or boarder.

Professional corporation means a corporation that is completely owned by one or more physicians and is operated for the purpose of conducting the practice of medicine, osteopathy dentistry, podiatry, optometry, or chiropractic, or is owned by other health care professionals as authorized by State law.

(c) *Applicability of the exclusion.* The exclusion applies to the following charges in the specified circumstances:

(1) *Physicians' services.* (i) Charges for physicians' services furnished by an immediate relative of the beneficiary or member of the beneficiary's household, even if the bill or claim is submitted by another individual or by an entity such as a partnership or a professional corporation.

(ii) Charges for services furnished incident to a physician's professional services (for example by the physician's nurse or technician), only if the physician who ordered or supervised the services has an excluded relationship to the beneficiary.

(2) *Services other than physicians' services.* (i) Charges imposed by an individually owned provider or supplier if the owner has an excluded relationship to the beneficiary; and

(ii) Charges imposed by a partnership if any of the partners has an excluded relationship to the beneficiary.

(d) *Exception to the exclusion.* The exclusion does not apply to charges imposed by a corporation other than a professional corporation.

§411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

(a) Routine physical checkups such as:

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury, except for screening mammography, colorectal cancer screening tests, screening pelvic exams, prostate cancer screening tests, glaucoma screening exams, or initial preventive physical examinations that meet the criteria specified in paragraphs (k)(6) through (k)(11) of this section.

(2) Examinations required by insurance companies, business establishments, government agencies, or other third parties.

(b) *Eyeglasses or contact lenses, except for:*

(1) Post-surgical prosthetic lenses customarily used during convalescence for eye surgery in which the lens of the eye was removed (e.g., cataract surgery);

(2) Prosthetic lenses for patients who lack the lens of the eye because of congenital absence or surgical removal; and

(3) One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery during which an intraocular lens is inserted.

(c) *Eye examinations* for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive error only and procedures performed in the course of any eye examination to determine the refractive state of the eyes, without regard to the reason for the performance of the refractive procedures. Refractive procedures are excluded even when performed in connection with otherwise covered diagnosis or treatment of illness or injury.

(d) *Hearing aids* or examination for the purpose of prescribing, fitting, or changing hearing aids.

(e) *Immunizations, except for—*

(1) Vaccinations or inoculations directly related to the treatment of an injury or direct exposure such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenom sera, or immune globulin;

(2) Pneumococcal vaccinations that are reasonable and necessary for the prevention of illness;

(3) Hepatitis B vaccinations that are reasonable and necessary for the prevention of illness for those individuals, as defined in § 410.63(a) of this chapter, who are at high or intermediate risk of contracting hepatitis B; and

(4) Influenza vaccinations that are reasonable and necessary for the prevention of illness.

(f) *Orthopedic shoes* or other supportive devices for the feet, *except when* shoes are integral parts of leg braces.

(g) *Custodial care, except as necessary* for the palliation or management of terminal illness, as provided in part 418 of this chapter. (Custodial care is any care that does not meet the requirements for coverage as SNF care as set forth in §§ 409.31 through 409.35 of this chapter.)

(h) *Cosmetic surgery and related services,* except as required for the prompt repair of accidental injury or to improve the functioning of a malformed body member.

(i) *Dental services* in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth, *except for* inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

(1) The individual's underlying medical condition and clinical status; or

(2) The severity of the dental procedures.[1]

(j) *Personal comfort services, except* as necessary for the palliation or management of terminal illness as provided in part 418 of this chapter. The use of a television set or a telephone are examples of personal *comfort* services.

(k) *Any services that are not reasonable and necessary* for one of the following purposes:

(1) For the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(2) In the case of hospice services, for the palliation or management of terminal illness, as provided in part 418 of this chapter.

(3) In the case of pneumococcal vaccine for the prevention of illness.

(4) In the case of the patient outcome assessment program established under section 1875(c) of the Act, for carrying out the purpose of that section.

(5) In the case of hepatitis B vaccine, for the prevention of illness for those individuals at high or intermediate risk of contracting hepatitis B. (Section 410.63(a) of this chapter sets forth criteria for identifying those individuals.)

(6) In the case of screening mammography, for the purpose of early detection of breast cancer subject to the conditions and limitations specified in § 410.34 of this chapter.

(7) In the case of colorectal cancer screening tests, for the purpose of early detection of colorectal cancer subject to the conditions and limitations specified in § 410.37 of this chapter.

(8) In the case of screening pelvic examinations, for the purpose of early detection of cervical or vaginal cancer subject to the conditions and limitations specified in § 410.56 of this chapter.

(9) In the case of prostate cancer screening tests, for the purpose of early detection of prostate cancer, subject to the conditions and limitations specified in § 410.39 of this chapter.

(10) In the case of screening exams for glaucoma, for the purpose of early detection of glaucoma, subject to the conditions and limitations specified in § 410.23 of this chapter.

(11) In the case of initial preventive physical examinations, with the goal of health promotion and disease prevention, subject to the conditions and limitations specified in § 410.16 of this chapter.

(l) *Foot care.* (1) *Basic rule.* Except as provided in paragraph (l)(2) of this section, any services furnished in connection with the following:

(i) *Routine foot care,* such as the cutting or removal of corns, or calluses, the trimming of nails, routine hygienic care (preventive maintenance care ordinarily within the realm of self care), and any service performed in the absence of localized illness, injury, or symptoms involving the feet.

[1] Before July 1981, inpatient hospital care in connection with dental procedures was covered only when required by the patient's underlying medical condition and clinical status.

(ii) *The evaluation or treatment of subluxations of the feet* regardless of underlying pathology. (Subluxations are structural misalignments of the joints, other than fractures or complete dislocations, that require treatment only by nonsurgical methods.

(iii) *The evaluation or treatment of flattened arches* (including the prescription of supportive devices) regardless of the underlying pathology.

(2) *Exceptions*. (i) Treatment of warts is not excluded.

(ii) Treatment of mycotic toenails may be covered if it is furnished no more often than every 60 days or the billing physician documents the need for more frequent treatment.

(iii) The services listed in paragraph (l)(1) of this section are not excluded if they are furnished—

(A) As an incident to, at the same time as, or as a necessary integral part of a primary covered procedure performed on the foot; or

(B) As initial diagnostic services (regardless of the resulting diagnosis) in connection with a specific symptom or complaint that might arise from a condition whose treatment would be covered.

(m) *Services to hospital patients*—(1) *Basic rule*. Except as provided in paragraph (m)(3) of this section, any service furnished to an inpatient of a hospital or to a hospital outpatient (as defined in §410.2 of this chapter) during an encounter (as defined in §410.2 of this chapter) by an entity other than the hospital unless the hospital has an arrangement (as defined in §409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients. As used in this paragraph (m)(1), the term ''hospital'' includes a CAH.

(2) *Scope of exclusion*. Services subject to exclusion from coverage under the provisions of this paragraph (m) include, but are not limited to, clinical laboratory services; pacemakers and other prostheses and prosthetic devices (other than dental) that replace all or part of an internal body organ (for example, intraocular lenses); artificial limbs, knees, and hips; equipment and supplies covered under the prosthetic device benefits; and services incident to a physician service.

(3) *Exceptions*. The following services are not excluded from coverage:

(i) Physicians' services that meet the criteria of §415.102(a) of this chapter for payment on a reasonable charge or fee schedule basis.

(ii) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act, that are furnished after December 31, 1990.

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse-midwife services, as defined in section 1861(ff) of the Act, that are furnished after December 31, 1990.

(v) Qualified psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

(vi) Services of an anesthetist, as defined in §410.69 of this chapter.

(n) *Certain services of an assistant-at-surgery*.

(1) Services of an assistant-at-surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate QIO or a carrier has approved the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition.

(2) Services on an assistant-at-surgery in a surgical procedure (or class of surgical procedures) for which assistants-at-surgery on average are used in fewer than 5 percent of such procedures nationally.

(o) *Experimental or investigational devices, except for certain devices*—

(1) Categorized by the FDA as a nonexperimental/investigational (Category B) device defined in §405.201(b) of this chapter; and

(2) Furnished in accordance with the FDA-approved protocols governing clinical trials.

(p) *Services furnished to SNF residents*—(1) *Basic rule*. Except as provided in paragraph (p)(2) of this section, any service furnished to a resident of an SNF during a covered Part A stay by an entity other than the SNF, unless the SNF has an arrangement (as defined in §409.3 of this chapter) with that entity to furnish that particular service to the SNF's residents. Services

subject to exclusion under this paragraph include, but are not limited to—

(i) Any physical, occupational, or speech-language therapy services, regardless of whether the services are furnished by (or under the supervision of) a physician or other health care professional, and regardless of whether the resident who receives the services is in a covered Part A stay; and

(ii) Services furnished as an incident to the professional services of a physician or other health care professional specified in paragraph (p)(2) of this section.

(2) *Exceptions*. The following services are not excluded from coverage, provided that the claim for payment includes the SNF's Medicare provider number in accordance with § 424.32(a)(5) of this chapter:

(i) Physicians' services that meet the criteria of § 415.102(a) of this chapter for payment on a fee schedule basis.

(ii) Services performed under a physician's supervision by a physician assistant who meets the applicable definition in section 1861(aa)(5) of the Act.

(iii) Services performed by a nurse practitioner or clinical nurse specialist who meets the applicable definition in section 1861(aa)(5) of the Act and is working in collaboration (as defined in section 1861(aa)(6) of the Act) with a physician.

(iv) Services performed by a certified nurse-midwife, as defined in section 1861(gg) of the Act.

(v) Services performed by a qualified psychologist, as defined in section 1861(ii) of the Act.

(vi) Services performed by a certified registered nurse anesthetist, as defined in section 1861(bb) of the Act.

(vii) Dialysis services and supplies, as defined in section 1861(s)(2)(F) of the Act, and those ambulance services that are furnished in conjunction with them.

(viii) Erythropoietin (EPO) for dialysis patients, as defined in section 1861(s)(2)(O) of the Act.

(ix) Hospice care, as defined in section 1861(dd) of the Act.

(x) An ambulance trip that initially conveys an individual to the SNF to be admitted as a resident, or that conveys an individual from the SNF in connection with one of the circumstances specified in paragraphs (p)(3)(i) through (p)(3)(iv) of this section as ending the individual's status as an SNF resident.

(xi) The transportation costs of electrocardiogram equipment (HCPCS code R0076), but only with respect to those electrocardiogram test services furnished during 1998.

(xii) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020; J9040–J9151; J9170–J9185; J9200–J9201; J9206–J9208; J9211; J9230–J9245; and J9265–J9600; and, as of January 1, 2004, by HCPCS codes A9522, A9523, A9533, and A9534.

(xiii) Those chemotherapy administration services identified, as of July 1, 1999, by HCPCS codes 36260–36262; 36489; 36530–36535; 36640; 36823; and 96405–96542.

(xiv) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440.

(xv) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999, by HCPCS codes L5050–L5340; L5500–L5611; L5613–L5986; L5988; L6050–L6370; L6400–6880; L6920–L7274; and L7362–L7366, which are delivered for a resident's use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

(3) *SNF resident defined*. For purposes of this paragraph, a beneficiary who is admitted to a Medicare-participating SNF is considered to be a resident of the SNF for the duration of the beneficiary's covered Part A stay. In addition, for purposes of the services described in paragraph (p)(1)(i) of this section, a beneficiary who is admitted to a Medicare-participating SNF is considered to be a resident of the SNF regardless of whether the beneficiary is in a covered Part A stay. Whenever the beneficiary leaves the facility, the beneficiary's status as an SNF resident for purposes of this paragraph (along with the SNF's responsibility to furnish or make arrangements for the services described in paragraph (p)(1) of this section) ends when one of the following events occurs—

(i) The beneficiary is admitted as an inpatient to a Medicare-participating hospital or CAH, or as a resident to another SNF;

(ii) The beneficiary receives services from a Medicare-participating home health agency under a plan of care;

(iii) The beneficiary receives outpatient services from a Medicare-participating hospital or CAH (but only with respect to those services that are beyond the general scope of SNF comprehensive care plans, as required under §483.20 of this chapter); or

(iv) The beneficiary is formally discharged (or otherwise departs) from the SNF, unless the beneficiary is readmitted (or returns) to that or another SNF by midnight of the day of departure.

(q) *Assisted suicide*. Any health care service used for the purpose of causing, or assisting to cause, the death of any individual. This does not pertain to the withholding or withdrawing of medical treatment or care, nutrition or hydration or to the provision of a service for the purpose of alleviating pain or discomfort, even if the use may increase the risk of death, so long as the service is not furnished for the specific purpose of causing death.

(r) A home health service (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) as defined in section 1861(m) of the Act furnished to an individual who is under a plan of care of an HHA, unless that HHA has submitted a claim for payment for such services.

[54 FR 41734, Oct. 11, 1989; 55 FR 1820, Jan. 19, 1990, as amended at 55 FR 22789, June 4, 1990; 55 FR 31185, Aug. 1, 1990; 57 FR 33897, July 31, 1992; 57 FR 36015, Aug. 12, 1992; 58 FR 30669, May 26, 1993; 59 FR 49834, Sept. 30, 1994; 60 FR 48424, Sept. 19, 1995; 60 FR 63188, Dec. 8, 1995; 62 FR 46037, Aug. 29, 1997; 62 FR 59101, Oct. 31, 1997; 63 FR 26308, May 12, 1998; 63 FR 35066, June 26, 1998; 64 FR 41682, July 30, 1999; 64 FR 59441, Nov. 2, 1999; 65 FR 18537, Apr. 7, 2000; 65 FR 41211, July 3, 2000; 65 FR 46796, July 31, 2000; 66 FR 32778, June 18, 2001; 66 FR 39600, July 31, 2001; 66 FR 48078, Sept. 17, 2001; 66 FR 55331, Nov. 1, 2001; 66 FR 58786, Nov. 23, 2001; 68 FR 46070, Aug. 4, 2003; 69 FR 66423, Nov. 15, 2004; 70 FR 45055, Aug. 4, 2005]

Subpart B—Insurance Coverage That Limits Medicare Payment: General Provisions

§411.20 Basis and scope.

(a) *Statutory basis*. (1) Section 1862(b)(2)(A)(i) of the Act precludes Medicare payment for services to the extent that payment has been made or can reasonably be expected to be made under a group health plan with respect to—

(i) A beneficiary entitled to Medicare on the basis of ESRD during the first 18 months of that entitlement;

(ii) A beneficiary who is age 65 or over, entitled to Medicare on the basis of age, and covered under the plan by virtue of his or her current employment status or the current employment status of a spouse of any age; or

(iii) A beneficiary who is under age 65, entitled to Medicare on the basis of disability, and covered under the plan by virtue of his or her current employment status or the current employment status of a family member.

(2) Section 1862(b)(2)(A)(ii) of the Act precludes Medicare payment for services to the extent that payment has been made or can reasonably be expected to be made promptly under any of the following:

(i) Workers' compensation.

(ii) Liability insurance.

(iii) No-fault insurance.

(b) *Scope*. This subpart sets forth general rules that apply to the types of insurance specified in paragraph (a) of this section. Other general rules that apply to group health plans are set forth in subpart E of this part.

[60 FR 45361, Aug. 31, 1995]

§411.21 Definitions.

In this subpart B and in subparts C through H of this part, unless the context indicates otherwise—

Conditional payment means a Medicare payment for services for which another payer is responsible, made either on the bases set forth in subparts C through H of this part, or because the intermediary or carrier did not know that the other coverage existed.

Coverage or *covered services*, when used in connection with third party payments, means services for which a

third party payer would pay if a proper claim were filed.

Monthly capitation payment means a comprehensive monthly payment that covers all physician services associated with the continuing medical management of a maintenance dialysis patient who dialyses at home or as an outpatient in an approved ESRD facility.

Plan means any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness.

Prompt or *promptly*, when used in connection with third party payments, except as provided in § 411.50, for payments by liability insurers, means payment within 120 days after receipt of the claim.

Proper claim means a claim that is filed timely and meets all other claim filing requirements specified by the plan, program, or insurer.

Secondary, when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be made under other coverage that is primary to Medicare.

Secondary payments means payments made for Medicare covered services or portions of services that are not payable under other coverage that is primary to Medicare.

Third party payer means an insurance policy, plan, or program that is primary to Medicare.

Third party payment means payment by a third party payer for services that are also covered under Medicare.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 45361, Aug. 31, 1995]

§ 411.23 Beneficiary's cooperation.

(a) If CMS takes action to recover conditional payments, the beneficiary must cooperate in the action.

(b) If CMS's recovery action is unsuccessful because the beneficiary does not cooperate, CMS may recover from the beneficiary.

§ 411.24 Recovery of conditional payments.

If a Medicare conditional payment is made, the following rules apply:

(a) *Release of information*. The filing of a Medicare claim by on or behalf of the beneficiary constitutes an express authorization for any entity, including State Medicaid and workers' compensation agencies, and data depositories, that possesses information pertinent to the Medicare claim to release that information to CMS. This information will be used only for Medicare claims processing and for coordination of benefits purposes.

(b) *Right to initiate recovery*. CMS may initiate recovery as soon as it learns that payment has been made or could be made under workers' compensation, any liability or no-fault insurance, or an employer group health plan.

(c) *Amount of recovery*. (1) If it is not necessary for CMS to take legal action to recover, CMS recovers the lesser of the following:

(i) The amount of the Medicare primary payment.

(ii) The full primary payment amount that the primary payer is obligated to pay under this part without regard to any payment, other than a full primary payment that the primary payer has paid or will make, or, in the case of a third party payment recipient, the amount of the third party payment.

(2) If it is necessary for CMS to take legal action to recover from the primary payer, CMS may recover twice the amount specified in paragraph (c)(1)(i) of this section.

(d) *Methods of recovery*. CMS may recover by direct collection or by offset against any monies CMS owes the entity responsible for refunding the conditional payment.

(e) *Recovery from third parties*. CMS has a direct right of action to recover from any entity responsible for making primary payment. This includes an employer, an insurance carrier, plan, or program, and a third party administrator.

(f) *Claims filing requirements*. (1) CMS may recover without regard to any claims filing requirements that the insurance program or plan imposes on the beneficiary or other claimant such as a time limit for filing a claim or a time limit for notifying the plan or program about the need for or receipt of services.

(2) However, CMS will not recover its payment for particular services in the face of a claims filing requirement unless it has filed a claim for recovery by the end of the year following the year in which the Medicare intermediary or carrier that paid the claim has notice that the third party is primary to Medicare for those particular services. (A notice received during the last three months of a year is considered received during the following year.)

(g) *Recovery from parties that receive third party payments.* CMS has a right of action to recover its payments from any entity, including a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment.

(h) *Reimbursement to Medicare.* If the beneficiary or other party receives a third party payment, the beneficiary or other party must reimburse Medicare within 60 days.

(i) *Special rules.* (1) In the case of liability insurance settlements and disputed claims under employer group health plans and no-fault insurance, the following rule applies: If Medicare is not reimbursed as required by paragraph (h) of this section, the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.

(2) The provisions of paragraph (i)(1) of this section also apply if a third party payer makes its payment to an entity other than Medicare when it is, or should be, aware that Medicare has made a conditional primary payment.

(3) In situations that involve procurement costs, the rule of §411.37(b) applies.

(j) *Recovery against Medicaid agency.* If a third party payment is made to a State Medicaid agency and that agency does not reimburse Medicare, CMS may reduce any Federal funds due the Medicaid agency (under title XIX of the Act) by an amount equal to the Medicare payment or the third party payment, whichever is less.

(k) *Recovery against Medicare contractor.* If a Medicare contractor, including an intermediary or carrier, also insures, underwrites, or administers as a third party administrator, a program or plan that is primary to Medicare, and does not reimburse Medicare, CMS may offset the amount owed against any funds due the intermediary or carrier under title XVIII of the Act or due the contractor under the contract.

(l) *Recovery when there is failure to file a proper claim.* (1) *Basic rule.* If Medicare makes a conditional payment with respect to services for which the beneficiary or provider or supplier has not filed a proper claim with a third party payer, and Medicare is unable to recover from the third party payer, Medicare may recover from the beneficiary or provider or supplier that was responsible for the failure to file a proper claim.

(2) *Exceptions:* (i) This rule does not apply in the case of liability insurance nor when failure to file a proper claim is due to mental or physical incapacity of the beneficiary.

(ii) CMS will not recover from providers or suppliers that are in compliance with the requirements of §489.20 of this chapter and can show that the reason they failed to file a proper claim is that the beneficiary, or someone acting on his or her behalf, failed to give, or gave erroneous, information regarding coverage that is primary to Medicare.

(m) *Interest charges.* (1) With respect to recovery of payments for items and services furnished before October 31, 1994, CMS charges interest, exercising common law authority in accordance with 45 CFR 30.13, consistent with the Federal Claims Collection Act (31 U.S.C. 3711).

(2) In addition to its common law authority with respect to recovery of payments for items and services furnished on or after October 31, 1994, CMS charges interest in accordance with section 1862(b)(2)(B)(i) of the Act. Under that provision—

(i) CMS may charge interest if reimbursement is not made to the appropriate trust fund before the expiration of the 60-day period that begins on the date on which notice or other information is received by CMS that payment has been or could be made under a primary plan;

(ii) Interest may accrue from the date when that notice or other information is received by CMS, is charged

until reimbursement is made, and is applied for full 30-day periods; and

(iii) The rate of interest is that provided at § 405.378(d) of this chapter.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 60 FR 45361, 45362, Aug. 31, 1995; 69 FR 45607, July 30, 2004]

§ 411.25 Third party payer's notice of mistaken Medicare primary payment.

(a) If a third party payer learns that CMS has made a Medicare primary payment for services for which the third party payer has made or should have made primary payment, it must give notice to that effect to the Medicare intermediary or carrier that paid the claim.

(b) The notice must describe the specific situation and the circumstances (including the particular type of insurance coverage as specified in § 411.20(a)) and, if appropriate, the time period during which the insurer is primary to Medicare.

(c) If a plan is self-insured and self-administered, the employer must give the notice to CMS. Otherwise, the insurer, underwriter, or third party administrator must give the notice.

[54 FR 41734, Oct. 11, 1989; as amended at 55 FR 1820, Jan. 19, 1990]

§ 411.26 Subrogation and right to intervene.

(a) *Subrogation.* With respect to services for which Medicare paid, CMS is subrogated to any individual, provider, supplier, physician, private insurer, State agency, attorney, or any other entity entitled to payment by a third party payer.

(b) *Right to intervene.* CMS may join or intervene in any action related to the events that gave rise to the need for services for which Medicare paid.

§ 411.28 Waiver of recovery and compromise of claims.

(a) CMS may waive recovery, in whole or in part, if the probability of recovery, or the amount involved, does not warrant pursuit of the claim.

(b) General rules applicable to compromise of claims are set forth in subpart F of part 401 and § 405.376 of this chapter.

(c) Other rules pertinent to recovery are contained in subpart C of part 405 of this chapter.

[54 FR 41734, Oct. 11, 1989, as amended at 61 FR 63749, Dec. 2, 1996]

§ 411.30 Effect of third party payment on benefit utilization and deductibles.

(a) *Benefit utilization.* Inpatient psychiatric hospital and SNF care that is paid for by a third party payer is not counted against the number of inpatient care days available to the beneficiary under Medicare Part A.

(b) *Deductibles.* Expenses for Medicare covered services that are paid for by third party payers are credited toward the Medicare Part A and Part B deductibles.

§ 411.31 Authority to bill third party payers for full charges.

(a) The fact that Medicare payments are limited to the DRG amount, or the reasonable charge, reasonable cost, capitation or fee schedule rate, does not affect the amount that a third party payer may pay.

(b) With respect to workers' compensation plans, no-fault insurers, and employer group health plans, a provider or supplier may bill its full charges and expect those charges to be paid unless there are limits imposed by laws other than title XVIII of the Act or by agreements with the third party payer.

§ 411.32 Basis for Medicare secondary payments.

(a) *Basic rules.* (1) Medicare benefits are secondary to benefits payable by a third party payer even if State law or the third party payer states that its benefits are secondary to Medicare benefits or otherwise limits its payments to Medicare beneficiaries.

(2) Except as provided in paragraph (b) of this section, Medicare makes secondary payments, within the limits specified in paragraph (c) of this section and in § 411.33, to supplement the third party payment if that payment is less than the charges for the services and, in the case of services paid on other than a reasonable charge basis, less than the gross amount payable by Medicare under § 411.33(e).

(b) *Exception.* Medicare does not make a secondary payment if the provider or supplier is either obligated to accept, or voluntarily accepts, as full payment, a third party payment that is less than its charges.

(c) *General limitation: Failure to file a proper claim.* When a provider or supplier, or a beneficiary who is not physically or mentally incapacitated, receives a reduced third party payment because of failure to file a proper claim, the Medicare secondary payment may not exceed the amount that would have been payable under § 411.33 if the third party payer had paid on the basis of a proper claim.

The provider, supplier, or beneficiary must inform CMS that a reduced payment was made, and the amount that would have been paid if a proper claim had been filed.

§ 411.33 Amount of Medicare secondary payment.

(a) *Services for which CMS pays on a Medicare fee schedule or reasonable charge basis.* The Medicare secondary payment is the lowest of the following:

(1) The actual charge by the supplier (or the amount the supplier is obligated to accept as payment in full if that is less than the charges) minus the amount paid by the third party payer.

(2) The amount that Medicare would pay if the services were not covered by a third party payer.

(3) The higher of the Medicare fee schedule, Medicare reasonable charge, or other amount which would be payable under Medicare (without regard to any applicable Medicare deductible or coinsurance amounts) or the third party payer's allowable charge (without regard to any deductible or co-insurance imposed by the policy or plan) minus the amount actually paid by the third party payer.

(b) *Example:* An individual received treatment from a physician for which the physician charged $175. The third party payer allowed $150 of the charge and paid 80 percent of this amount or $120. The Medicare fee schedule for this treatment is $125. The individual's Part B deductible had been met. As secondary payer, Medicare pays the lowest of the following amounts:

(1) Excess of actual charge minus the third party payment: $175 − 120=$55.

(2) Amount Medicare would pay if the services were not covered by a third party payer: .80×$125=$100.

(3) Third party payer's allowable charge without regard to its coinsurance (since that amount is higher than the Medicare fee schedule in this case) minus amount paid by the third party payer: $150 − 120=$30.

The Medicare payment is $30.

(c)–(d) [Reserved]

(e) *Services reimbursed on a basis other than fee schedule, reasonable charge, or monthly capitation rate.* The Medicare secondary payment is the lowest of the following:

(1) The gross amount payable by Medicare (that is, the amount payable without considering the effect of the Medicare deductible and coinsurance or the payment by the third party payer), minus the applicable Medicare deductible and coinsurance amounts.

(2) The gross amount payable by Medicare, minus the amount paid by the third party payer.

(3) The provider's charges (or the amount the provider is obligated to accept as payment in full, if that is less than the charges), minus the amount payable by the third party payer.

(4) The provider's charges (or the amount the provider is obligated to accept as payment in full if that is less than the charges), minus the applicable Medicare deductible and coinsurance amounts.

(f) *Examples:* (1) A hospital furnished 7 days of inpatient hospital care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services totaled $2,800. The third party payer paid $2,360. No part of the Medicare inpatient hospital deductible of $520 had been met. If the gross amount payable by Medicare in this case is $2,700, then as secondary payer, Medicare pays the lowest of the following amounts:

(i) The gross amount payable by Medicare minus the Medicare inpatient hospital deductible: $2,700 − $520=$2,180.

(ii) The gross amount payable by Medicare minus the third party payment: $2,700 − $2,360=$340.

(iii) The provider's charges minus the third party payment: $2,800 – $2,360=$440.

(iv) The provider's charges minus the Medicare deductible: $2,800 – $520=$2,280. Medicare's secondary payment is $340 and the combined payment made by the third party payer and Medicare on behalf of the beneficiary is $2,700. The $520 deductible was satisfied by the third party payment so that the beneficiary incurred no out-of-pocket expenses.

(2) A hospital furnished 1 day of inpatient hospital care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services totalled $750. The third party payer paid $450. No part of the Medicare inpatient hospital deductible had been met previously. The third party payment is credited toward that deductible. If the gross amount payable by Medicare in this case is $850, then as secondary payer, Medicare pays the lowest of the following amounts:

(i) The gross amount payable by Medicare minus the Medicare deductible: $850 – $520=$330.

(ii) The gross amount payable by Medicare minus the third party payment: $850 – $450=$400.

(iii) The provider's charges minus the third party payment: $750 – $450=$300.

(iv) The provider's charges minus the Medicare deductible: $750 – $520=$230. Medicare's secondary payment is $230, and the combined payment made by the third party payer and Medicare on behalf of the beneficiary is $680. The hospital may bill the beneficiary $70 (the $520 deductible minus the $450 third party payment). This fully discharges the beneficiary's deductible obligation.

(3) An ESRD beneficiary received 8 dialysis treatments for which a facility charged $160 per treatment for a total of $1,280. No part of the beneficiary's $75 Part B deductible had been met. The third party payer paid $1,024 for Medicare-covered services. The composite rate per dialysis treatment at this facility is $131 or $1,048 for 8 treatments. As secondary payer, Medicare pays the lowest of the following:

(i) The gross amount payable by Medicare minus the applicable Medicare deductible and coinsurance: $1,048 – $75 – $194.60=$778.40. (The coinsurance is calculated as follows: $1,048 composite rate – $75 deductible=$973×.20=$194.60).

(ii) The gross amount payable by Medicare minus the third party payment: $1,048 – $1,024=$24.

(iii) The provider's charges minus the third party payment: $1,280 – $1,024=$256.

(iv) The provider's charge minus the Medicare deductible and coinsurance: $1,280 – $75 – $194.60=1010.40. Medicare pays $24. The beneficiary's Medicare deductible and coinsurance were met by the third party payment.

(4) A hospital furnished 5 days of inpatient care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services were $4,000 and the gross amount payable was $3,500. The provider agreed to accept $3,000 from the third party as payment in full. The third party payer paid $2,900 due to a deductible requirement under the third party plan. Medicare considers the amount the provider is obligated to accept as full payment ($3,000) to be the provider charges. The Medicare secondary payment is the lowest of the following:

(i) The gross amount payable by Medicare minus the Medicare inpatient deductible: $3,500 – $520=$2,980.

(ii) The gross amount payable by Medicare minus the third party payment: $3,500 – $2,900=$600.

(iii) The provider's charge minus the third party payment: $3,000 – $2,900=$100.

(iv) The provider's charges minus the Medicare inpatient deductible: $3,000 – $520=$2,480. The Medicare secondary payment is $100. When Medicare is the secondary payer, the combined payment made by the third party payer and Medicare on behalf of the beneficiary is $3,000. The beneficiary has no liability for Medicare-covered services since the third party payment satisfied the $520 deductible.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 60 FR 45362, Aug. 31, 1995]

§ 411.35 Limitations on charges to a beneficiary or other party when a workers' compensation plan, a no-fault insurer, or an employer group health plan is primary payer.

(a) *Definition*. As used in this section *Medicare-covered services* means services for which Medicare benefits are payable or would be payable except for the Medicare deductible and coinsurance provisions and the amounts payable by the third party payer.

(b) *Applicability*. This section applies when a workers' compensation plan, a no-fault insurer or an employer group health plan is primary to Medicare.

(c) *Basic rule*. Except as provided in paragraph (d) of this section, the amounts the provider or supplier may collect or seek to collect, for the Medicare-covered services from the beneficiary or any entity other than the workers' compensation plan, the no-fault insurer, or the employer plan and Medicare, are limited to the following:

(1) The amount paid or payable by the third party payer to the beneficiary. If this amount exceeds the amount payable by Medicare (without regard to deductible or coinsurance), the provider or supplier may retain the third party payment in full without violating the terms of the provider agreement or the conditions of assignment.

(2) The amount, if any, by which the applicable Medicare deductible and coinsurance amounts exceed any third party payment made or due to the beneficiary or to the provider or supplier for the medical services.

(3) The amount of any charges that may be made to a beneficiary under § 413.35 of this chapter when cost limits are applied to the services, or under § 489.32 of this chapter when the services are partially covered, but only to the extent that the third party payer is not responsible for those charges.

(d) *Exception*. The limitations of paragraph (c) of this section do not apply if the services were furnished by a supplier that is not a participating supplier and has not accepted assignment for the services or claimed payment under § 424.64 of this chapter.

§ 411.37 Amount of Medicare recovery when a third party payment is made as a result of a judgment or settlement.

(a) *Recovery against the party that received payment*—(1) *General rule*. Medicare reduces its recovery to take account of the cost of procuring the judgment or settlement, as provided in this section, if—

(i) Procurement costs are incurred because the claim is disputed; and

(ii) Those costs are borne by the party against which CMS seeks to recover.

(2) *Special rule*. If CMS must file suit because the party that received payment opposes CMS's recovery, the recovery amount is as set forth in paragraph (e) of this section.

(b) *Recovery against the third party payer*. If CMS seeks recovery from the third party payer, in accordance with § 411.24(i), the recovery amount will be no greater than the amount determined under paragraph (c) or (d) or (e) of this section.

(c) *Medicare payments are less than the judgment or settlement amount*. If Medicare payments are less than the judgment or settlement amount, the recovery is computed as follows:

(1) Determine the ratio of the procurement costs to the total judgment or settlement payment.

(2) Apply the ratio to the Medicare payment. The product is the Medicare share of procurement costs.

(3) Subtract the Medicare share of procurement costs from the Medicare payments. The remainder is the Medicare recovery amount.

(d) *Medicare payments equal or exceed the judgment or settlement amount*. If Medicare payments equal or exceed the judgment or settlement amount, the recovery amount is the total judgment or settlement payment minus the total procurement costs.

(e) *CMS incurs procurement costs because of opposition to its recovery*. If CMS must bring suit against the party that received payment because that party opposes CMS's recovery, the recovery amount is the lower of the following:

(1) Medicare payment.

(2) The total judgment or settlement amount, minus the party's total procurement cost.

Subpart C—Limitations on Medicare Payment for Services Covered Under Workers' Compensation

§ 411.40 General provisions.

(a) *Definition.* *''Workers' compensation plan of the United States''* includes the workers' compensation plans of the 50 States, the District of Columbia, American Samoa, Guam, Puerto Rico, and the Virgin Islands, as well as the systems provided under the Federal Employees' Compensation Act and the Longshoremen's and Harbor Workers' Compensation Act.

(b) *Limitations on Medicare payment.* (1) Medicare does not pay for any services for which—

(i) Payment has been made, or can reasonably be expected to be made promptly under a workers' compensation law or plan of the United States or a state; or

(ii) Payment could be made under the Federal Black Lung Program, but is precluded solely because the provider of the services has failed to secure, from the Department of Labor, a provider number to include in the claim.

(2) If the payment for a service may not be made under workers' compensation because the service is furnished by a source not authorized to provide that service under the particular workers' compensation program, Medicare pays for the service if it is a covered service.

(3) Medicare makes secondary payments in accordance with § 411.32 and § 411.33.

§ 411.43 Beneficiary's responsibility with respect to workers' compensation.

(a) The beneficiary is responsible for taking whatever action is necessary to obtain any payment that can reasonably be expected under workers' compensation.

(b) Except as specified in § 411.45(a), Medicare does not pay until the beneficiary has exhausted his or her remedies under workers' compensation.

(c) Except as specified in § 411.45(b), Medicare does not pay for services that would have been covered under workers' compensation if the beneficiary had filed a proper claim.

(d) However, if a claim is denied for reasons other than not being a proper claim, Medicare pays for the services if they are covered under Medicare.

§ 411.45 Basis for conditional Medicare payment in workers' compensation cases.

A conditional Medicare payment may be made under either of the following circumstances:

(a) The beneficiary has filed a proper claim for workers' compensation benefits, but the intermediary or carrier determines that the workers' compensation carrier will not pay promptly. This includes cases in which a workers' compensation carrier has denied a claim.

(b) The beneficiary, because of physical or mental incapacity, failed to file a proper claim.

§ 411.46 Lump-sum payments.

(a) *Lump-sum commutation of future benefits.* If a lump-sum compensation award stipulates that the amount paid is intended to compensate the individual for all future medical expenses required because of the work-related injury or disease, Medicare payments for such services are excluded until medical expenses related to the injury or disease equal the amount of the lump-sum payment.

(b) *Lump-sum compromise settlement.* (1) A lump-sum compromise settlement is deemed to be a workers' compensation payment for Medicare purposes, even if the settlement agreement stipulates that there is no liability under the workers' compensation law or plan.

(2) If a settlement appears to represent an attempt to shift to Medicare the responsibility for payment of medical expenses for the treatment of a work-related condition, the settlement will not be recognized. For example, if the parties to a settlement attempt to maximize the amount of disability benefits paid under workers' compensation by releasing the workers' compensation carrier from liability for medical expenses for a particular condition even though the facts show that the condition is work-related, Medicare

will not pay for treatment of that condition.

(c) *Lump-sum compromise settlement: Effect on services furnished before the date of settlement.* Medicare pays for medical expenses incurred before the lump-sum compromise settlement only to the extent specified in §411.47.

(d) *Lump-sum compromise settlement: Effect on payment for services furnished after the date of settlement*—(1) *Basic rule.* Except as specified in paragraph (d)(2) of this section, if a lump-sum compromise settlement forecloses the possibility of future payment of workers' compensation benefits, medical expenses incurred after the date of the settlement are payable under Medicare.

(2) *Exception.* If the settlement agreement allocates certain amounts for specific future medical services, Medicare does not pay for those services until medical expenses related to the injury or disease equal the amount of the lump-sum settlement allocated to future medical expenses.

§411.47 Apportionment of a lump-sum compromise settlement of a workers' compensation claim.

(a) *Determining amount of compromise settlement considered as a payment for medical expenses.* (1) If a compromise settlement allocates a portion of the payment for medical expenses and also gives reasonable recognition to the income replacement element, that apportionment may be accepted as a basis for determining Medicare payments.

(2) If the settlement does not give reasonable recognition to both elements of a workers' compensation award or does not apportion the sum granted, the portion to be considered as payment for medical expenses is computed as follows:

(i) Determine the ratio of the amount awarded (less the reasonable and necessary costs incurred in procuring the settlement) to the total amount that would have been payable under workers' compensation if the claim had not been compromised.

(ii) Multiply that ratio by the total medical expenses incurred as a result of the injury or disease up to the date of the settlement. The product is the amount of the workers' compensation settlement to be considered as payment for medical expenses.

Example: As the result of a work injury, an individual suffered loss of income and incurred medical expenses for which the total workers' compensation payment would have been $24,000 if the case had not been compromised. The medical expenses amounted to $18,000. The workers' compensation carrier made a settlement with the beneficiary under which it paid $8,000 in total. A separate award was made for legal fees. Since the workers' compensation compromise settlement was for one-third of the amount which would have been payable under workers' compensation had the case not been compromised ($8,000/$24,000=⅓), the workers' compensation compromise settlement is considered to have paid for one-third of the total medical expenses (⅓×$18,000=$6,000).

(b) *Determining the amount of the Medicare overpayment.* When conditional Medicare payments have been made, and the beneficiary receives a compromise settlement payment, the Medicare overpayment is determined as set forth in this paragraph (b). The amount of the workers' compensation payment that is considered to be for medical expenses (as determined under paragraph (a) of this section) is applied, at the workers' compensation rate of payment prevailing in the particular jurisdiction, in the following order:

(1) First to any beneficiary payments for services payable under workers' compensation but not covered under Medicare.

(2) Then to any beneficiary payments for services payable under workers' compensation and also covered under Medicare Part B. (These include deductible and coinsurance amounts and, in unassigned cases, the charge in excess of the reasonable charge.)

(3) Last to any beneficiary payments for services payable under workers' compensation and also covered under Medicare Part A. (These include Part A deductible and coinsurance amounts and charges for services furnished after benefits are exhausted.)

The difference between the amount of the workers' compensation payment for medical expenses and any beneficiary payments constitutes the Medicare overpayment. The beneficiary is liable for that amount.

Example: In the example in paragraph (a) of this section, it was determined that the workers' compensation settlement paid for $6,000 of the total medical expenses. The $18,000 in medical expenses included $1,500 in charges for services not covered under Medicare, $7,500 in charges for services covered under Medicare Part B, and $9,000 in hospital charges for services covered under Medicare Part A. All charges were at the workers' compensation payment rate, that is, in amounts the provider or supplier must accept as payment in full.

The Medicare reasonable charge for physicians' services was $7,000 and Medicare paid $5,600 (80 percent of the reasonable charge). The Part B deductible had been met. The Medicare payment rate for the hospital services was $8,000. Medicare paid the hospital $7,480 ($8,000—the Part A deductible of $520).

In this situation, the beneficiary's payments totalled $3,920:

Services not covered under Medicare	$1,500
Excess of physicians' charges over reasonable charges	500
Medicare Part B coinsurance	1,400
Part A deductible	520
Total	3,920

The Medicare overpayment, for which the beneficiary is liable, would be $2,080 ($6,000–$3,920).

Subpart D—Limitations on Medicare Payment for Services Covered Under Liability or No-Fault Insurance

§ 411.50 General provisions.

(a) *Limits on applicability*. The provisions of this subpart C do not apply to any services required because of accidents that occurred before December 5, 1980.

(b) *Definitions*.

Automobile means any self-propelled land vehicle of a type that must be registered and licensed in the State in which it is owned.

Liability insurance means insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property. It includes, but is not limited to, automobile liability insurance, uninsured motorist insurance, underinsured motorist insurance, homeowners' liability insurance, malpractice insurance, product liability insurance, and general casualty insurance.

Liability insurance payment means a payment by a liability insurer, or an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by any individual or other entity that carries liability insurance or is covered by a self-insured plan.

No-fault insurance means insurance that pays for medical expenses for injuries sustained on the property or premises of the insured, or in the use, occupancy, or operation of an automobile, regardless of who may have been responsible for causing the accident. This insurance includes but is not limited to automobile, homeowners, and commercial plans. It is sometimes called ''medical payments coverage'', ''personal injury protection'', or ''medical expense coverage''.

Prompt or *promptly*, when used in connection with payment by a liability insurer means payment within 120 days after the earlier of the following:

(1) The date a claim is filed with an insurer or a lien is filed against a potential liability settlement.

(2) The date the service was furnished or, in the case of inpatient hospital services, the date of discharge.

Self-insured plan means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier. The term includes a plan of an individual or other entity engaged in a business, trade, or profession, a plan of a non-profit organization such as a social, fraternal, labor, educational, religious, or professional organization, and the plan established by the Federal government to pay liability claims under the Federal Tort Claims Act.

Underinsured motorist insurance means insurance under which the policyholder's level of protection against losses caused by another is extended to compensate for inadequate coverage in the other party's policy or plan.

Uninsured motorist insurance means insurance under which the policyholder's insurer will pay for damages caused by a motorist who has no automobile liability insurance or who carries less than the amount of insurance required by law, or is underinsured.

(c) *Limitation on payment for services covered under no-fault insurance*. Except as provided under §§ 411.52 and 411.53

with respect to conditional payments. Medicare does not pay for the following:

(1) Services for which payment has been made or can reasonably be expected to be made promptly under automobile no-fault insurance.

(2) Services furnished on or after November 13, 1989 for which payment has been made or can reasonably be expected to be made promptly under any no-fault insurance other than automobile no-fault.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990]

§ 411.51 Beneficiary's responsibility with respect to no-fault insurance.

(a) The beneficiary is responsible for taking whatever action is necessary to obtain any payment that can reasonably be expected under no-fault insurance.

(b) Except as specified in § 411.53, Medicare does not pay until the beneficiary has exhausted his or her remedies under no-fault insurance.

(c) Except as specified in § 411.53, Medicare does not pay for services that would have been covered by the no-fault insurance if the beneficiary had filed a proper claim.

(d) However, if a claim is denied for reasons other than not being a proper claim, Medicare pays for the services if they are covered under Medicare.

§ 411.52 Basis for conditional Medicare payment in liability cases.

If CMS has information that services for which Medicare benefits have been claimed are for treatment of an injury or illness that was allegedly caused by another party, a conditional Medicare payment may be made.

§ 411.53 Basis for conditional Medicare payment in no-fault cases.

A conditional Medicare payment may be made in no-fault cases under either of the following circumstances:

(a) The beneficiary, or the provider or supplier, has filed a proper claim for no-fault insurance benefits but the intermediary or carrier determines that the no-fault insurer will not pay promptly for any reason other than the circumstances described in § 411.32(a)(1). This includes cases in which the no-fault insurance carrier has denied the claim.

(b) The beneficiary, because of physical or mental incapacity, failed to meet a claim-filing requirement stipulated in the policy.

§ 411.54 Limitation on charges when a beneficiary has received a liability insurance payment or has a claim pending against a liability insurer.

(a) *Definition*. As used in this section, *Medicare-covered services* means services for which Medicare benefits are payable or would be payable except for applicable Medicare deductible and coinsurance provisions. Medicare benefits are payable notwithstanding potential liability insurance payments, but are recoverable in accordance with § 411.24.

(b) *Applicability*. This section applies when a beneficiary has received a liability insurance payment or has a claim pending against a liability insurer for injuries or illness allegedly caused by another party.

(c) *Itemized bill*. A hospital must, upon request, furnish to the beneficiary or his or her representative an itemized bill of the hospital's charges.

(d) *Exception—(1) Prepaid health plans*. If the services were furnished through an organization that has a contact under section 1876 of the Act (that is, an HMO or CMP), or through an organization that is paid under section 1833(a)(1)(A) of the Act (that is, through an HCPP) the rules of § 417.528 of this chapter apply.

(2) *Special rules for Oregon*. For the State of Oregon, because of a court decision, and in the absence of a reversal on appeal or a statutory clarification overturning the decision, there are the following special rules:

(i) The provider or supplier may elect to bill a liability insurer or place a lien against the beneficiary's liability settlement for Medicare covered services, rather than bill only Medicare for Medicare covered services, if the liability insurer pays within 120 days after the earlier of the following dates:

(A) The date the provider or supplier files a claim with the insurer or places a lien against a potential liability settlement.

(B) The date the services were provided or, in the case of inpatient hospital services, the date of discharge.

(ii) If the liability insurer does not pay within the 120-day period, the provider or supplier:

(A) Must withdraw its claim with the liability insurer and/or withdraw its lien against a potential liability settlement.

(B) May only bill Medicare for Medicare covered services.

(C) May bill the beneficiary only for applicable Medicare deductible and coinsurance amounts plus the amount of any charges that may be made to a beneficiary under 413.35 of this chapter (when cost limits are applied to these services) or under 489.32 of this chapter (when services are partially covered).

[54 FR 41734, Oct. 11, 1989, as amended at 68 FR 43942, July 25, 2003]

Subpart E—Limitations on Payment for Services Covered Under Group Health Plans: General Provisions

SOURCE: 60 FR 45362, Aug. 31, 1995, unless otherwise noted.

§ 411.100 Basis and scope.

(a) *Statutory basis.* (1) Section 1862(b) of the Act provides in part that Medicare is secondary payer, under specified conditions, for services covered under any of the following:

(i) Group health plans of employers that employ at least 20 employees and that cover Medicare beneficiaries age 65 or older who are covered under the plan by virtue of the individual's current employment status with an employer or the current employment status of a spouse of any age. (Section 1862(b)(1)(A))

(ii) Group health plans (without regard to the number of individuals employed and irrespective of current employment status) that cover individuals who have ESRD. Except as provided in § 411.163, group health plans are always primary payers throughout the first 18 months of ESRD-based Medicare eligibility or entitlement. (Section 1862(b)(1)(C))

(iii) Large group health plans (that is, plans of employers that employ at least 100 employees) and that cover Medicare beneficiaries who are under age 65, entitled to Medicare on the basis of disability, and covered under the plan by virtue of the individual's or a family member's current employment status with an employer. (Section 1862(b)(1)(B))

(2) Sections 1862(b)(1)(A), (B), and (C) of the Act provide that group health plans and large group health plans may not take into account that the individuals described in paragraph (a)(1) of this section are entitled to Medicare on the basis of age or disability, or eligible for, or entitled to Medicare on the basis of ESRD.

(3) Section 1862(b)(1)(A)(i)(II) of the Act provides that group health plans of employers of 20 or more employees must provide to any employee or spouse age 65 or older the same benefits, under the same conditions, that it provides to employees and spouses under 65. The requirement applies regardless of whether the individual or spouse 65 or older is entitled to Medicare.

(4) Section 1862(b)(1)(C)(ii) of the Act provides that group health plans may not differentiate in the benefits they provide between individuals who have ESRD and other individuals covered under the plan on the basis of the existence of ESRD, the need for renal dialysis, or in any other manner. Actions that constitute ''differentiating'' are listed in § 411.161(b).

(b) *Scope.* This subpart sets forth general rules pertinent to—

(1) Medicare payment for services that are covered under a group health plan and are furnished to certain beneficiaries who are entitled on the basis of ESRD, age, or disability.

(2) The prohibition against taking into account Medicare entitlement based on age or disability, or Medicare eligibility or entitlement based on ESRD.

(3) The prohibition against differentiation in benefits between individuals who have ESRD and other individuals covered under the plan.

(4) The requirement to provide to those 65 or over the same benefits under the same conditions as are provided to those under 65.

(5) The appeals procedures for group health plans that CMS determines are nonconforming plans.

§411.101 Definitions.

As used in this subpart and in subparts F through H of this part—

COBRA stands for Consolidated Omnibus Budget Reconciliation Act of 1985.

Days means calendar days.

Employee (subject to the special rules in §411.104) means an individual who—

(1) Is working for an employer; or

(2) Is not working for an employer but is receiving payments that are subject to FICA taxes, or would be subject to FICA taxes except that the employer is exempt from those taxes under the Internal Revenue Code.

Employer means, in addition to individuals (including self-employed persons) and organizations engaged in a trade or business, other entities exempt from income tax such as religious, charitable, and educational institutions, the governments of the United States, the individual States, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the District of Columbia, and the agencies, instrumentalities, and political subdivisions of these governments.

FICA stands for the Federal Insurance Contributions Act, the law that imposes social security taxes on employers and employees under section 21 of the Internal Revenue Code.

Group health plan (GHP) means any arrangement made by one or more employers or employee organizations to provide health care directly or through other methods such as insurance or reimbursement, to current or former employees, the employer, others associated or formerly associated with the employer in a business relationship, or their families, that—

(1) Is of, or contributed to by, one or more employers or employee organizations.

(2) If it involves more than one employer or employee organization, provides for common administration.

(3) Provides substantially the same benefits or the same benefit options to all those enrolled under the arrangement.

The term includes self-insured plans, plans of governmental entities (Federal, State and local), and employee organization plans; that is, union plans, employee health and welfare funds or other employee organization plans. The term also includes employee-pay-all plans, which are plans under the auspices of one or more employers or employee organizations but which receive no financial contributions from them. The term does not include a plan that is unavailable to employees; for example, a plan only for self-employed persons.

IRC stands for Internal Revenue Code.

IRS stands for Internal Revenue Service.

Large group health plan (LGHP) means a GHP that covers employees of either—

(1) A single employer or employee organization that employed at least 100 full-time or part-time employees on 50 percent or more of its regular business days during the previous calendar year; or

(2) Two or more employers, or employee organizations, at least one of which employed at least 100 full-time or part-time employees on 50 percent or more of its regular business days during the previous calendar year.

MSP stands for Medicare secondary payer.

Multi-employer plan means a plan that is sponsored jointly by two or more employers (sometimes called a multiple-employer plan) or by employers and unions (sometimes under the Taft-Hartley law).

Self-employed person encompasses consultants, owners of businesses, and directors of corporations, and members of the clergy and religious orders who are paid for their services by a religious body or other entity.

Similarly situated individual means—

(1) In the case of employees, other employees enrolled or seeking to enroll in the plan; and

(2) In the case of other categories of individuals, other persons in any of those categories who are enrolled or seeking to enroll in the plan.

§ 411.102 Basic prohibitions and requirements.

(a) *ESRD*. (1) A group health plan of any size—(i) May not take into account the ESRD-based Medicare eligibility or entitlement of any individual who is covered or seeks to be covered under the plan; and

(ii) May not differentiate in the benefits it provides between individuals with ESRD and other individuals covered under the plan, on the basis of the existence of ESRD, or the need for dialysis, or in any other manner.

(2) The prohibitions of paragraph (a) of this section do not prohibit a plan from paying benefits secondary to Medicare after the first 18 months of ESRD-based eligibility or entitlement.

(b) *Age*. A GHP of an employer or employee organization of at least 20 employees—

(1) May not take into account the age-based Medicare entitlement of an individual or spouse age 65 or older who is covered (or seeks to be covered) under the plan by virtue of current employment status; and

(2) Must provide, to employees age 65 or older and to spouses age 65 or older of employees of any age, the same benefits under the same conditions as it provides to employees and spouses under age 65.

(c) *Disability*. A GHP of an employer or employee organization of at least 100 employees may not take into account the disability-based Medicare entitlement of any individual who is covered (or seeks to be covered) under the plan by virtue of current employment status.

§ 411.103 Prohibition against financial and other incentives.

(a) *General rule*. An employer or other entity (for example, an insurer) is prohibited from offering Medicare beneficiaries financial or other benefits as incentives not to enroll in, or to terminate enrollment in, a GHP that is, or would be, primary to Medicare. This prohibition precludes offering to Medicare beneficiaries an alternative to the employer primary plan (for example, coverage of prescription drugs) unless the beneficiary has primary coverage other than Medicare. An example would be primary coverage through his own or a spouse's employer.

(b) *Penalty for violation*. (1) Any entity that violates the prohibition of paragraph (a) of this section is subject to a civil money penalty of up to $5,000 for each violation; and

(2) The provisions of section 1128A of the Act (other than subsections (a) and (b)) apply to the civil money penalty of up to $5,000 in the same manner as the provisions apply to a penalty or proceeding under section 1128A(a).

§ 411.104 Current employment status.

(a) *General rule*. An individual has current employment status if—

(1) The individual is actively working as an employee, is the employer (including a self-employed person), or is associated with the employer in a business relationship; or

(2) The individual is not actively working and—

(i) Is receiving disability benefits from an employer for up to 6 months (the first 6 months of employer disability benefits are subject to FICA taxes); or

(ii) Retains employment rights in the industry and has not had his employment terminated by the employer, if the employer provides the coverage (or has not had his membership in the employee organization terminated, if the employee organization provides the coverage), is not receiving disability benefits from an employer for more than 6 months, is not receiving disability benefits from Social Security, and has GHP coverage that is not pursuant to COBRA continuation coverage (26 U.S.C. 4980B; 29 U.S.C. 1161–1168; 42 U.S.C. 300bb–1 *et seq.*). Whether or not the individual is receiving pay during the period of nonwork is not a factor.

(b) *Persons who retain employment rights*. For purposes of paragraph (a)(2) of this section, persons who retain employment rights include but are not limited to—

(1) Persons who are furloughed, temporarily laid off, or who are on sick leave;

(2) Teachers and seasonal workers who normally do not work throughout the year; and

(3) Persons who have health coverage that extends beyond or between active

employment periods; for example, based on an hours bank arrangement. (Active union members often have hours bank coverage.)

(c) *Coverage by virtue of current employment status*. An individual has coverage by virtue of current employment status with an employer if—

(1) the individual has GHP or LGHP coverage based on employment, including coverage based on a certain number of hours worked for that employer or a certain level of commissions earned from work for that employer at any time; and

(2) the individual has current employment status with that employer, as defined in paragraph (a) of this section.

(d) *Special rule: Self-employed person*. A self-employed individual is considered to have GHP or LGHP coverage by virtue of current employment status during a particular tax year only if, during the preceding tax year, the individual's net earnings, from work in that year related to the employer that offers the group health coverage, are at least equal to the amount specified in section 211(b)(2) of the Act, which defines ''self-employment income'' for social security purposes.

(e) *Special Rule: members of religious orders and members of clergy*. (1) *Members of religious orders who have not taken a vow of poverty*. A member of a religious order who has *not* taken a vow of poverty is considered to have current employment status with the religious order if—

(i) The religious order pays FICA taxes on behalf of that member; or

(ii) The individual is receiving cash remuneration from the religious order.

(2) *Members of religious orders who have taken a vow of poverty*. A member of a religious order whose members are required to take a vow of poverty is not considered to be employed by the order if the services he or she performs as a member of the order are considered employment only because the order elects social security coverage under section 3121(r) of the IRC. This exemption applies retroactively to services performed as a member of the order, beginning with the effective dates of the MSP provisions for the aged and the disabled, respectively. The exemption does not apply to services performed for employers outside of the order.

(3) *Members of the clergy*. A member of the clergy is considered to have current employment status with a church or other religious organization if the individual is receiving cash remuneration from the church or other religious organization for services rendered.

(f) *Special rule: Delayed compensation subject to FICA taxes*. An individual who is not working is not considered an employee solely on the basis of receiving delayed compensation payments for previous periods of work even if those payments are subject to FICA taxes (or would be subject to FICA taxes if the employer were not exempt from paying those taxes). For example, an individual who is not working in 1993 and receives payments subject to FICA taxes for work performed in 1992 is not considered to be an employee in 1993 solely on the basis of receiving those payments.

§411.106 Aggregation rules.

The following rules apply in determining the number and size of employers, as required by the MSP provisions for the aged and disabled:

(a) All employers that are treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC) of 1986 (26 U.S.C. 52 (a) and (b)) are treated as a single employer.

(b) All employees of the members of an affiliated service group (as defined in section 414(m) of the IRC (26 U.S.C. 414m)) are treated as employed by a single employer.

(c) Leased employees (as defined in section 414(n)(2) of the IRC (26 U.S.C. 414(n)(2)) are treated as employees of the person for whom they perform services to the same extent as they are treated under section 414(n) of the IRC.

(d) In applying the IRC provisions identified in this section, CMS relies upon regulations and decisions of the Secretary of the Treasury respecting those provisions.

§411.108 Taking into account entitlement to Medicare.

(a) *Examples of actions that constitute ''taking into account''*. Actions by GHPs

or LGHPs that constitute taking into account that an individual is entitled to Medicare on the basis of ESRD, age, or disability (or eligible on the basis of ESRD) include, but are not limited to, the following:

(1) Failure to pay primary benefits as required by subparts F, G, and H of this part 411.

(2) Offering coverage that is secondary to Medicare to individuals entitled to Medicare.

(3) Terminating coverage because the individual has become entitled to Medicare, except as permitted under COBRA continuation coverage provisions (26 U.S.C. 4980B(f)(2)(B)(iv); 29 U.S.C. 1162.(2)(D); and 42 U.S.C. 300bb–2.(2)(D)).

(4) In the case of a LGHP, denying or terminating coverage because an individual is entitled to Medicare on the basis of disability without denying or terminating coverage for similarly situated individuals who are not entitled to Medicare on the basis of disability.

(5) Imposing limitations on benefits for a Medicare entitled individual that do not apply to others enrolled in the plan, such as providing less comprehensive health care coverage, excluding benefits, reducing benefits, charging higher deductibles or coinsurance, providing for lower annual or lifetime benefit limits, or more restrictive pre-existing illness limitations.

(6) Charging a Medicare entitled individual higher premiums.

(7) Requiring a Medicare entitled individual to wait longer for coverage to begin.

(8) Paying providers and suppliers less for services furnished to a Medicare beneficiary than for the same services furnished to an enrollee who is not entitled to Medicare.

(9) Providing misleading or incomplete information that would have the effect of inducing a Medicare entitled individual to reject the employer plan, thereby making Medicare the primary payer. An example of this would be informing the beneficiary of the right to accept or reject the employer plan but failing to inform the individual that, if he or she rejects the plan, the plan will not be permitted to provide or pay for secondary benefits.

(10) Including in its health insurance cards, claims forms, or brochures distributed to beneficiaries, providers, and suppliers, instructions to bill Medicare first for services furnished to Medicare beneficiaries without stipulating that such action may be taken only when Medicare is the primary payer.

(11) Refusing to enroll an individual for whom Medicare would be secondary payer, when enrollment is available to similarly situated individuals for whom Medicare would not be secondary payer.

(b) *Permissible actions.* (1) If a GHP or LGHP makes benefit distinctions among various categories of individuals (distinctions unrelated to the fact that the individual is disabled, based, for instance, on length of time employed, occupation, or marital status), the GHP or LGHP may make the same distinctions among the same categories of individuals entitled to Medicare whose plan coverage is based on current employment status. For example, if a GHP or LGHP does not offer coverage to employees who have worked less than one year and who are *not* entitled to Medicare on the basis of disability or age, the GHP or LGHP is not required to offer coverage to employees who have worked less than one year and who *are* entitled to Medicare on the basis of disability or age.

(2) A GHP or LGHP may pay benefits secondary to Medicare for an aged or disabled beneficiary who has current employment status if the plan coverage is COBRA continuation coverage because of reduced hours of work. Medicare is primary payer for this beneficiary because, although he or she has current employment status, the GHP coverage is by virtue of the COBRA law rather than by virtue of the current employment status.

(3) A GHP may terminate COBRA continuation coverage of an individual who becomes entitled to Medicare on the basis of ESRD, when permitted under the COBRA provisions.

[60 FR 45362, Aug. 31, 1995; 60 FR 53876, Oct. 18, 1995]

§ 411.110 Basis for determination of nonconformance.

(a) A ''determination of nonconformance'' is a CMS determination that a

GHP or LGHP is a nonconforming plan as provided in this section.

(b) CMS makes a determination of nonconformance for a GHP or LGHP that, at any time during a calendar year, fails to comply with any of the following statutory provisions:

(1) The prohibition against taking into account that a beneficiary who is covered or seeks to be covered under the plan is entitled to Medicare on the basis of ESRD, age, or disability, or eligible on the basis of ESRD.

(2) The nondifferentiation clause for individuals with ESRD.

(3) The equal benefits clause for the working aged.

(4) The obligation to refund conditional Medicare primary payments.

(c) CMS may make a determination of nonconformance for a GHP or LGHP that fails to respond to a request for information, or to provide correct information, either voluntarily or in response to a CMS request, on the plan's primary payment obligation with respect to a given beneficiary, if that failure contributes to either or both of the following:

(1) Medicare erroneously making a primary payment.

(2) A delay or foreclosure of CMS's ability to recover an erroneous primary payment.

§411.112 Documentation of conformance.

(a) *Acceptable documentation.* CMS may require a GHP or LGHP to demonstrate that it has complied with the Medicare secondary payer provisions and to submit supporting documentation by an official authorized to act on behalf of the entity, under penalty of perjury. The following are examples of documentation that may be acceptable:

(1) A copy of the employer's plan or policy that specifies the services covered, conditions of coverage, benefit levels and limitations with respect to persons entitled to Medicare on the basis of ESRD, age, or disability as compared to the provisions applicable to other enrollees and potential enrollees.

(2) An explanation of the plan's allegation that it does not owe CMS any amount CMS claims the plan owes as repayment for conditional or mistaken Medicare primary payments.

(b) *Lack of acceptable documentation.* If a GHP or LGHP fails to provide acceptable evidence or documentation that it has complied with the MSP prohibitions and requirements set forth in §411.110, CMS may make a determination of nonconformance for both the year in which the services were furnished and the year in which the request for information was made.

§411.114 Determination of nonconformance.

(a) *Starting dates for determination of nonconformance.* CMS's authority to determine nonconformance of GHPs begins on the following dates:

(1) On January 1, 1987 for MSP provisions that affect the disabled.

(2) On December 20, 1989 for MSP provisions that affect ESRD beneficiaries and the working aged.

(3) On August 10, 1993 for failure to refund mistaken Medicare primary payments.

(b) *Special rule for failure to repay.* A GHP that fails to comply with §411.110 (a)(1), (a)(2), or (a)(3) in a particular year is nonconforming for that year. If, in a subsequent year, that plan fails to repay the resulting mistaken primary payments (in accordance with §411.110(a)(4)), the plan is also nonconforming for the subsequent year. For example, if a plan paid secondary for the working aged in 1991, that plan was nonconforming for 1991. If in 1994 CMS identifies mistaken primary payments attributable to the 1991 violation, and the plan refuses to repay, it is also nonconforming for 1994.

§411.115 Notice of determination of nonconformance.

(a) *Notice to the GHP or LGHP.* (1) If CMS determines that a GHP or an LGHP is nonconforming with respect to a particular calendar year, CMS mails to the plan written notice of the following:

(i) The determination.

(ii) The basis for the determination.

(iii) The right of the parties to request a hearing.

(iv) An explanation of the procedure for requesting a hearing.

(v) The tax that may be assessed by the IRS in accordance with section 5000 of the IRC.

(vi) The fact that if none of the parties requests a hearing within 65 days from the date of its notice, the determination is binding on all parties unless it is reopened in accordance with § 411.126.

(2) The notice also states that the plan must, within 30 days from the date on its notice, submit to CMS the names and addresses of all employers and employee organizations that contributed to the plan during the calendar year for which CMS has determined nonconformance.

(b) *Notice to contributing employers and employee organizations.* CMS mails written notice of the determination, including all the information specified in paragraph (a)(1) of this section, to all contributing employers and employee organizations already known to CMS or identified by the plan in accordance with paragraph (a)(2) of this section. Employers and employee organizations have 65 days from the date of their notice to request a hearing.

§ 411.120 Appeals.

(a) *Parties to the determination.* The parties to the determination are CMS, the GHP or LGHP for which CMS determined nonconformance, and any employers or employee organizations that contributed to the plan during the calendar year for which CMS determined nonconformance.

(b) *Request for hearing.* (1) A party's request for hearing must be in writing (not in facsimile or other electronic medium) and in the manner stipulated in the notice of nonconformance; it must be filed within 65 days from the date on the notice.

(2) The request may include rationale showing why the parties believe that CMS's determination is incorrect and supporting documentation.

(3) A request is considered filed on the date it is received by the appropriate office, as shown by the receipt date stamped on the request.

§ 411.121 Hearing procedures.

(a) *Nature of hearing.* (1) If any of the parties requests a hearing within 65 days from the date on the notice of the determination of nonconformance, the CMS Administrator appoints a hearing officer.

(2) If no party files a request within the 65-day period, the initial determination of nonconformance is binding upon all parties unless it is reopened in accordance with § 411.126.

(3) If more than one party requests a hearing the hearing officer conducts a single hearing in which all parties may participate.

(4) *On the record review.* Ordinarily, the hearing officer makes a decision based upon review of the data and documents on which CMS based its determination of nonconformance and any other documentation submitted by any of the parties within 65 days from the date on the notice.

(5) *Oral hearing.* The hearing officer may provide for an oral hearing either on his or her own motion or in response to a party's request if the party demonstrates to the hearing officer's satisfaction that an oral hearing is necessary. Within 30 days of receipt of the request, the hearing officer gives all known parties written notice of the request and whether the request for oral hearing is granted.

(b) *Notice of time and place of oral hearing.* If the hearing officer provides an oral hearing, he or she gives all known parties written notice of the time and place of the hearing at least 30 days before the scheduled date.

(c) *Prehearing discovery.* (1) The hearing officer may permit prehearing discovery if it is requested by a party at least 10 days before the scheduled date of the hearing.

(2) If the hearing officer approves the request, he or she—

(i) Provides a reasonable time for inspection and reproduction of documents; and

(ii) In ruling on discovery matters, is guided by the Federal Rules of Civil Procedure. (28 U.S.C.A. Rules 26–37)

(3) The hearing officer's orders on all discovery matters are final.

(d) *Conduct of hearing.* The hearing officer determines the conduct of the hearing, including the order in which the evidence and the allegations are presented.

(e) *Evidence at hearing.* (1) The hearing officer inquires into the matters at

issue and may receive from all parties documentary and other evidence that is pertinent and material, including the testimony of witnesses, and evidence that would be inadmissible in a court of law.

(2) Evidence may be received at any time before the conclusion of the hearing.

(3) The hearing officer gives the parties opportunity for submission and consideration of evidence and arguments and, in ruling on the admissibility of evidence, excludes irrelevant, immaterial, or unduly repetitious evidence.

(4) The hearing officer's ruling on admissibility of evidence is final and not subject to further review.

(f) *Subpoenas.* (1) The hearing officer may, either on his or her own motion or upon the request of any party, issue subpoenas for either or both of the following if they are reasonably necessary for full presentation of the case:

(i) The attendance and testimony of witnesses.

(ii) The production of books, records, correspondence, papers, or other documents that are relevant and material to any matter at issue.

(2) A party that wishes the issuance of a subpoena must, at least 10 days before the date fixed for the hearing, file with the hearing officer a written request that identifies the witnesses or documents to be produced and describes the address or location in sufficient detail to permit the witnesses or documents to be found.

(3) The request for a subpoena must state the pertinent facts that the party expects to establish by the witnesses or documents and whether those facts could be established by other evidence without the use of a subpoena.

(4) The hearing officer issues the subpoenas at his or her discretion, and CMS assumes the cost of the issuance and the fees and mileage of any subpoenaed witness, in accordance with section 205(d) of the Act (42 U.S.C. 405(d)).

(g) *Witnesses.* Witnesses at the hearing testify under oath or affirmation, unless excused by the hearing officer for cause. The hearing officer may examine the witnesses and shall allow the parties to examine and cross-examine witnesses.

(h) *Record of hearing.* A complete record of the proceedings at the hearing is made and transcribed in all cases. It is made available to the parties upon request. The record is not closed until a decision has been issued.

(i) *Sources of hearing officer's authority.* In the conduct of the hearing, the hearing officer complies with all the provisions of title XVIII of the Act and implementing regulations, as well as with CMS Rulings issued under §401.108 of this chapter. The hearing officer gives great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

§411.122 Hearing officer's decision.

(a) *Timing.* (1) If the decision is based on a review of the record, the hearing officer mails the decision to all known parties within 120 days from the date of receipt of the request for hearing.

(2) If the decision is based on an oral hearing, the hearing officer mails the decision to all known parties within 120 days from the conclusion of the hearing.

(b) *Basis, content, and distribution of hearing decision.* (1) The written decision is based on substantial evidence and contains findings of fact, a statement of reasons, and conclusions of law.

(2) The hearing officer mails a copy of the decision to each of the parties, by certified mail, return receipt requested, and includes a notice that the administrator may review the hearing decision at the request of a party or on his or her own motion.

(c) *Effect of hearing decision.* The hearing officer's decision is the final Departmental decision and is binding upon all parties unless the Administrator chooses to review that decision in accordance with §411.124 or it is reopened by the hearing officer in accordance with §411.126.

§411.124 Administrator's review of hearing decision.

(a) *Request for review.* A party's request for review of a hearing officer's decision must be in writing (not in facsimile or other electronic medium) and must be received by the Administrator

within 25 days from the date on the decision.

(b) *Office of the Attorney Advisor responsibility*. The Office of the Attorney Advisor examines the hearing officer's decision, the requests made by any of the parties or CMS, and any submission made in accordance with the provisions of this section in order to assist the Administrator in deciding whether to review the decision.

(c) *Administrator's discretion*. The Administrator may—

(1) Review or decline to review the hearing officer's decision;

(2) Exercise this discretion on his or her own motion or in response to a request from any of the parties; and

(3) Delegate review responsibility to the Deputy Administrator. (As used in this section, the term ''Administrator'' includes ''Deputy Administrator'' if review responsibility has been delegated.)

(d) *Basis for decision to review*. In deciding whether to review a hearing officer's decision, the Administrator considers—

(1) Whether the decision—

(i) Is based on a correct interpretation of law, regulation, or CMS Ruling;

(ii) Is supported by substantial evidence;

(iii) Presents a significant policy issue having a basis in law and regulations;

(iv) Requires clarification, amplification, or an alternative legal basis for the decision; and

(v) Is within the authority provided by statute, regulation, or CMS Ruling; and

(2) Whether review may lead to the issuance of a CMS Ruling or other directive needed to clarify a statute or regulation.

(e) *Notice of decision to review or not to review*. (1) The Administrator gives all parties prompt written notice of his or her decision to review or not to review.

(2) The notice of a decision to review identifies the specific issues the Administrator will consider.

(f) *Response to notice of decision to review*. (1) Within 20 days from the date on a notice of the Administrator's decision to review a hearing officer's decision, any of the parties may file with the Administrator any or all of the following:

(i) Proposed findings and conclusions.

(ii) Supporting views or exceptions to the hearing officer's decision.

(iii) Supporting reasons for the proposed findings and exceptions.

(iv) A rebuttal to another party's request for review or to other submissions already filed with the Administrator.

(2) The submissions must be limited to the issues the Administrator has decided to review and confined to the record established by the hearing officer.

(3) All communications from the parties concerning a hearing officer's decision being reviewed by the Administrator must be in writing (not in facsimile or other electronic medium) and must include a certification that copies have been sent to all other parties.

(4) The Administrator does not consider any communication that does not meet the requirements of this paragraph.

(g) *Administrator's review decision*. (1) The Administrator bases his or her decision on the following:

(i) The entire record developed by the hearing officer.

(ii) Any materials submitted in connection with the hearing or under paragraph (f) of this section.

(iii) Generally known facts not subject to reasonable dispute.

(2) The Administrator mails copies of the review decision to all parties within 120 days from the date of the hearing officer's decision.

(3) The Administrator's review decision may affirm, reverse, or modify the hearing decision or may remand the case to the hearing officer.

(h) *Basis and effect of remand*. (1) *Basis*. The bases for remand do not include the following:

(i) Evidence that existed at the time of the hearing and that was known or could reasonably have been expected to be known.

(ii) A court case that was either not available at the time of the hearing or was decided after the hearing.

(iii) Change of the parties' representation.

(iv) An alternative legal basis for an issue in dispute.

(2) *Effect of remand.* (i) The Administrator may instruct the hearing officer to take further action with respect to the development of additional facts or new issues or to consider the applicability of laws or regulations other than those considered during the hearing.

(ii) The hearing officer takes the action in accordance with the Administrator's instructions in the remand notice and again issues a decision.

(iii) The Administrator may review or decline to review the hearing officer's remand decision in accordance with the procedures set forth in this section.

(i) *Finality of decision.* The Administrator's review decision, or the hearing officer's decision following remand, is the final Departmental decision and is binding on all parties unless the Administrator chooses to review the decision in accordance with this section, or the decision is reopened in accordance with §411.126.

§411.126 Reopening of determinations and decisions.

(a) A determination that a GHP or LGHP is a nonconforming GHP or the decision or revised decision of a hearing officer or of the CMS Administrator may be reopened within 12 months from the date on the notice of determination or decision or revised decision, for any reason by the entity that issued the determination or decision.

(b) The decision to reopen or not to reopen is not appealable.

§411.130 Referral to Internal Revenue Service (IRS).

(a) *CMS responsibility.* After CMS determines that a plan has been a nonconforming GHP in a particular year, it refers its determination to the IRS, but only after the parties have exhausted all CMS appeal rights with respect to the determination.

(b) *IRS responsibility.* The IRS administers section 5000 of the IRC, which imposes a tax on employers (other than governmental entities) and employee organizations that contribute to a nonconforming GHP. The tax is equal to 25 percent of the employer's or employee organization's expenses, incurred during the calendar year in which the plan is a nonconforming GHP, for each GHP, both conforming and nonconforming, to which the employer or employee organization contributes.

Subpart F—Special Rules: Individuals Eligible or Entitled on the Basis of ESRD, Who Are Also Covered Under Group Health Plans

§411.160 Scope.

This subpart sets forth special rules that apply to individuals who are eligible for, or entitled to, Medicare on the basis of ESRD. (Section 406.13 of this chapter contains the rules for eligibility and entitlement based on ESRD.)

[60 FR 45367, Aug. 31, 1995]

§411.161 Prohibition against taking into account Medicare eligibility or entitlement or differentiating benefits.

(a) *Taking into account.* (1) *Basic rule.* A GHP may not take into account that an individual is eligible for or entitled to Medicare benefits on the basis of ESRD during the coordination period specified in §411.162(b) and (c). Examples of actions that constitute taking into account Medicare entitlement are listed in §411.108(a).

(2) *Applicability.* This prohibition applies for ESRD-based Medicare eligibility to the same extent as for ESRD-based Medicare entitlement. An individual who has ESRD but who has not filed an application for entitlement to Medicare on that basis is eligible for Medicare based on ESRD for purposes of paragraphs (b)(2) and (c)(2) through (c)(4) of §411.162 if the individual meets the other requirements of §406.13 of this chapter.

(3) *Relation to COBRA continuation coverage.* This rule does not prohibit the termination of GHP coverage under title X of COBRA when termination of that coverage is expressly permitted, upon entitlement to Medicare, under 26 U.S.C. 4980B(f)(2)(B)(iv); 29 U.S.C. 1162.(2)(D); or 42 U.S.C. 300bb–2.(2)(D).[1]

[1] COBRA requires that certain group health plans offer continuation of plan coverage for 18 to 36 months after the occurrence of certain ''qualifying events,'' including loss of

Continued

(Situations in which Medicare is secondary to COBRA continuation coverage are set forth in § 411.162(a)(3).)

(b) *Nondifferentiation.* (1) A GHP may not differentiate in the benefits it provides between individuals who have ESRD and others enrolled in the plan, on the basis of the existence of ESRD, or the need for renal dialysis, or in any other manner.

(2) GHP actions that constitute differentiation in plan benefits (and that may also constitute ''taking into account'' Medicare eligibility or entitlement) include, but are not limited to the following:

(i) Terminating coverage of individuals with ESRD, when there is no basis for such termination unrelated to ESRD (such as failure to pay plan premiums) that would result in termination for individuals who do not have ESRD.

(ii) Imposing on persons who have ESRD, but not on others enrolled in the plan, benefit limitations such as less comprehensive health plan coverage, reductions in benefits, exclusions of benefits, a higher deductible or coinsurance, a longer waiting period, a lower annual or lifetime benefit limit, or more restrictive preexisting illness limitations.

(iii) Charging individuals with ESRD higher premiums.

(iv) Paying providers and suppliers less for services furnished to individuals who have ESRD than for the same services furnished to those who do not have ESRD, such as paying 80 percent of the Medicare rate for renal dialysis on behalf of a plan enrollee who has ESRD and the usual, reasonable and customary charge for renal dialysis on behalf of an enrollee who does not have ESRD.

(v) Failure to cover routine maintenance dialysis or kidney transplants, when a plan covers other dialysis services or other organ transplants.

(c) *Uniform Limitations on particular services permissible.* A plan is not prohibited from limiting covered utilization of a particular service as long as the limitation applies uniformly to all plan enrollees. For instance, if a plan limits its coverage of renal dialysis sessions to 30 per year for all plan enrollees, the plan would not be differentiating in the benefits it provides between plan enrollees who have ESRD and those who do not.

(d) *Benefits secondary to Medicare.* (1) The prohibition against differentiation of benefits does not preclude a plan from paying benefits secondary to Medicare after the expiration of the coordination period described in § 411.162(b) and (c), but a plan may not otherwise differentiate, as described in paragraph (b) of this section, in the benefits it provides.

(2) Example—

Mr. Smith works for employer A, and he and his wife are covered through employer A's GHP (Plan A). Neither is eligible for Medicare nor has ESRD. Mrs. Smith works for employer B, and is also covered by employer B's plan (Plan B). Plan A is more comprehensive than Plan B and covers certain items and services which Plan B does not cover, such as prescription drugs. If Mrs. Smith obtains a medical service, Plan B pays primary and Plan A pays secondary. That is, Plan A covers Plan B copayment amounts and items and services that Plan A covers but that Plan B does not.

Mr. Jones also works for employer A, and he and his wife are covered by Plan A. Mrs. Jones does not have other GHP coverage. Mrs. Jones develops ESRD and becomes entitled to Medicare on that basis. Plan A pays primary to Medicare during the first 18 months of Medicare entitlement based on ESRD. When Medicare becomes the primary payer, the plan converts Mrs. Jones' coverage to a Medicare supplement policy. That policy pays Medicare deductible and coinsurance amounts but does not pay for items and services not covered by Medicare, which plan A would have covered. That conversion is impermissible because the plan is providing a lower level of coverage for Mrs. Jones, who has ESRD, than it provides for Mrs. Smith, who does not. In other words, if Plan A pays

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employment or reduction of employment hours. Those are events that otherwise would result in loss of group health plan coverage unless the individual is given the opportunity to elect, and does so elect, to continue plan coverage at his or her own expense. With one exception, the COBRA amendments expressly permit termination of continuation coverage upon entitlement to Medicare. The exception is that the plan may not terminate continuation coverage of an individual (and his or her qualified dependents) if the individual retires on or before the date the employer substantially eliminates regular plan coverage by filing for Chapter 11 bankruptcy (26 U.S.C. 4980B(g)(1)(D) and 29 U.S.C. 1167.(3)(C)).

secondary to primary payers other than Medicare, it must provide the same level of secondary benefits when Medicare is primary in order to comply with the nondifferentiation provision.

[60 FR 45368, Aug. 31, 1995]

§411.162 Medicare benefits secondary to group health plan benefits.

(a) *General provisions.* (1) *Basic rule.* Except as provided in §411.163 (with respect to certain individuals who are also entitled on the basis of age or disability), Medicare is secondary to any GHP (including a retirement plan), with respect to benefits that are payable to an individual who is entitled to Medicare on the basis of ESRD, for services furnished during any coordination period determined in accordance with paragraphs (b) and (c) of this section. (No Medicare benefits are payable on behalf of an individual who is eligible but not yet entitled.)

(2) *Medicare benefits secondary without regard to size of employer and beneficiary's employment status.* The size of employer and employment status requirements of the MSP provisions for the aged and disabled do not apply with respect to ESRD beneficiaries.

(3) *COBRA continuation coverage.* Medicare is secondary payer for benefits that a GHP—

(i) Is required to keep in effect under COBRA continuation requirements (as explained in the footnote to §411.161(a)(3)), even after the individual becomes entitled to Medicare; or

(ii) Voluntarily keeps in effect after the individual becomes entitled to Medicare on the basis of ESRD, even though not obligated to do so under the COBRA provisions.

(4) *Medicare payments during the coordination period.* During the coordination period, CMS makes Medicare payments as follows:

(i) Primary payments only for Medicare covered services that are—

(A) Furnished to Medicare beneficiaries who have declined to enroll in the GHP;

(B) Not covered under the plan;[1]

(C) Covered under the plan but not available to particular enrollees because they have exhausted their benefits; or

(D) Furnished to individuals whose COBRA continuation coverage has been terminated because of the individual's Medicare entitlement.

(ii) Secondary payments, within the limits specified in §§411.32 and 411.33, to supplement the amount paid by the GHP if that plan pays only a portion of the charge for the services.

(b) *Beginning of coordination period.* (1) For individuals who start a course of maintenance dialysis or who receive a kidney transplant before December 1989, the coordination period begins with the earlier of—

(i) The month in which the individual initiated a regular course of renal dialysis; or

(ii) In the case of an individual who received a kidney transplant, the first month in which the individual became entitled to Medicare, or, if earlier, the first month for which the individual would have been entitled to Medicare benefits if he or she had filed an application for such benefits.

(2) For individuals other than those specified in paragraph (b)(1) of this section, the coordination period begins with the earlier of—

(i) The first month in which the individual becomes entitled to Medicare part A on the basis of ESRD; or

(ii) The first month the individual would have become entitled to Medicare part A on the basis of ESRD if he or she had filed an application for such benefits.

(c) *End of coordination period.* (1) For individuals who start a regular course of renal dialysis or who receive a kidney transplant before December 1989, the coordination period ends with the earlier of the end of the 12th month of dialysis or the end of the 12th month of a transplant. The 12th month of dialysis may be any time from the 9th month through the 12th month of Medicare entitlement, depending on the extent to which the individual was subject to a waiting period before becoming entitled to Medicare.

(2) The coordination period for the following individuals ends with the earlier of the 12th month of eligibility or the 12th month of entitlement to Medicare part A:

[1] CMS does not pay if noncoverage of services constitutes differentiation as prohibited by §411.161(b).

(i) Individuals, other than those specified in paragraph (c)(1) of this section, who became entitled to Medicare part A solely on the basis of ESRD during December 1989 and January 1990.

(ii) Individuals, other than those specified in paragraph (c)(1) of this section, who could have become entitled to Medicare Part A solely on the basis of ESRD during December 1989 and January 1990 if they had filed an application.

(iii) Individuals who become entitled to Medicare part A on the basis of ESRD after September 1997.

(iv) Individuals who can become entitled to Medicare part A on the basis of ESRD after September 1997.

(3) The coordination period for the following individuals ends with the earlier of the end of the 18th month of eligibility or the 18th month of entitlement to Medicare part A:

(i) Individuals, other than those specified in paragraph (c)(1) of this section, who become entitled to Medicare part A on the basis of ESRD from February 1990 through April 1997.

(ii) Individuals, other than those specified in paragraph (c)(1) of this section, who could become entitled to Medicare part A on the basis of ESRD from February 1990 through April 1997 if they would file an application.

(4) The coordination periods for the following individuals ends September 30, 1998:

(i) Individuals who become entitled to Medicare part A on the basis of ESRD from May 1997, through September 1997.

(ii) Individuals who could become entitled to Medicare part A on the basis of ESRD from May 1997, through September 1997, if they would file an application.

(d) *Examples*. Based on the rules specified in paragraphs (b) and (c) of this section and the rules specified in § 406.13 of this subchapter, the following examples illustrate how to determine, in different situations, the number of months during which Medicare is secondary payer.

(1) An individual began dialysis on November 4, 1989. He did not initiate a course in self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare on February 1, 1990. Since this individual began dialysis before December 1989, the 12-month period began with the first month of dialysis, November 1989, and ended October 31, 1990. The coordination period in this case is 9 months, February 1990 through October 1990.

(2) An individual began dialysis on January 29, 1990. He did not initiate a course in self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare on April 1, 1990. Since the individual began dialysis after November 1989, and became entitled to Medicare after January 1990, the coordination period began with the first month of entitlement, April 1990, and ended September 30, 1991, the end of the 18th month of entitlement.

(3) An individual began a regular course of maintenance dialysis on February 10, 1990. He did not initiate a course of self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare on May 1, 1990. Medicare is secondary payer from May 1, 1990 through October 1991, a total of 18 months.

(4) The same facts exist as in the example under paragraph (d)(3), except that the individual began a course of self-dialysis training during the first 3 calendar months of dialysis. Thus, the effective date of his Medicare entitlement is February 1, 1990, and Medicare is secondary payer from February 1, 1990 through July 1991, a total of 18 months.

(5) An individual began dialysis on September 15, 1990. He did not initiate a course of self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare effective December 1, 1990. Medicare is secondary payer from December 1, 1990 through May 1992, a total of 18 months.

(6) An individual began dialysis on November 17, 1990. He initiates a course of self-dialysis training in January 1991, and thus becomes entitled to Medicare effective November 1, 1990.

Medicare is secondary payer from November 1, 1990, through April 1992, a total of 18 months.

(7) An individual began a regular course of dialysis on December 10, 1990. He does not initiate a course of self-dialysis training nor does he receive a kidney transplant. He decides to delay his enrollment in Medicare because his employer group health plan pays charges in full and he does not wish to incur part B premiums at this time. However, in March 1992, he files for part A and part B Medicare entitlement, and stipulates that he wants his Medicare entitlement to be effective March 1, 1992 (one year later than he could have become entitled). Since this individual could have been entitled to Medicare as early as March 1, 1991, Medicare is secondary payer only from March 1, 1992, through August 1992, a period of 6 months.

(While Medicare is secondary payer for only the last 6 months of this period, the Medicare program is effectively secondary payer for the full coordination period, due to the fact that the individual delayed his Medicare enrollment on account of his employer plan coverage and Medicare made no payments at all during the deferred period.)

(8) The same facts exist as in the example under paragraph (d)(7) of this section, except that the individual defers Medicare entitlement beyond August 1992. (For purposes of this example, Medicare entitlement is not retroactive, but rather takes effect after August 1992.) There would be no period during which Medicare is secondary payer in this situation. This is because Medicare entitlement does not begin until after the 18-month period expires as specified in paragraph (c)(3)(ii) of this section. Medicare would become primary payer as of the effective date of Medicare entitlement. The employer plan is required to pay primary from December 1, 1990, through August 1992, a total of 21 months.

(9) An individual becomes entitled to Medicare on December 1, 1997. The employer plan is primary payer, and Medicare is secondary payer, from December 1, 1997, through November 30, 1998, a period of 12 months. Medicare becomes primary payer on December 1, 1998, because the extension of the coordination period from 12 to 18 months applies only to items and services furnished before October 1, 1998.

(10) An individual becomes entitled to Medicare on August 1, 1997. Medicare is secondary payer from August 1, 1997, through September 30, 1998, a period of 14 months. Medicare becomes primary payer on October 1, 1998, because the coordination period has expired.

(e) [Reserved]

(f) *Determinations for subsequent periods of ESRD eligibility*. If an individual has more than one period of eligibility based on ESRD, a coordination period will be determined for each period of eligibility in accordance with this section.

[57 FR 36015, Aug. 12, 1992; 57 FR 45113, Sept. 30, 1992. Redesignated and amended at 60 FR 45362, 45368, Aug. 31, 1995]

§411.163 Coordination of benefits: Dual entitlement situations.

(a) *Basic rule*. Coordination of benefits is governed by this section if an individual is eligible for or entitled to Medicare on the basis of ESRD and also entitled on the basis of age or disability.

(b) *Specific rules.*[1] (1) *Coordination period ended before August 1993*. If the first 18 months of ESRD-based eligibility or entitlement ended before August 1993, Medicare was primary payer from the first month of dual eligibility or entitlement, regardless of when dual eligibility or entitlement began.

(2) *First month of ESRD-based eligibility or entitlement and first month of dual eligibility/entitlement after February 1992 and before August 10, 1993*. Except as provided in paragraph (b)(4) of this section, if the first month of ESRD-

[1] A lawsuit was filed in United States District Court for the District of Columbia on May 5, 1995 (*National Medical Care, Inc.* v. *Shalala*, Civil Action No. 95–0860), challenging the implementation of one aspect of the OBRA '93 provisions with respect to group health plan retirement coverage. The court issued a preliminary injunction order on June 6, 1995, which enjoins the Secretary from applying the rule contained in §411.163(b)(4) for items and services furnished between August 10, 1993 and April 24, 1995, pending the court's decision on the merits. CMS will modify the rules, if required, based on the final ruling by the court.

based eligibility or entitlement and first month of dual eligibility/entitlement were after February 1992 and before August 10, 1993, Medicare—

(i) Is primary payer from the first month of dual eligibility/entitlement through August 9, 1993;

(ii) Is secondary payer from August 10, 1993, through the 18th month of ESRD-based eligibility or entitlement; and

(iii) Again becomes primary payer after the 18th month of ESRD-based eligibility or entitlement.

(3) *First month of ESRD-based eligibility or entitlement after February 1992 and first month of dual eligibility/entitlement after August 9, 1993.* Except as provided in paragraph (b)(4) of this section, if the first month of ESRD-based eligibility or entitlement is after February 1992, and the first month of dual eligibility/entitlement is after August 9, 1993, the rules of § 411.162(b) and (c) apply; that is, Medicare—

(i) Is secondary payer during the first 18 months of ESRD-based eligibility or entitlement; and

(ii) Becomes primary after the 18th month of ESRD-based eligibility or entitlement.

(4) *Medicare continues to be primary after an aged or disabled beneficiary becomes eligible on the basis of ESRD.* (i) *Applicability of the rule.* Medicare remains the primary payer when an individual becomes eligible for Medicare based on ESRD if all of the following conditions are met:

(A) The individual is already entitled on the basis of age or disability when he or she becomes eligible on the basis of ESRD.

(B) The MSP prohibition against ''taking into account'' age-based or disability-based entitlement does not apply because plan coverage was not ''by virtue of current employment status'' or the employer had fewer than 20 employees (in the case of the aged) or fewer than 100 employees (in the case of the disabled).

(C) The plan is paying secondary to Medicare because the plan had justifiably taken into account the age-based or disability-based entitlement.

(ii) *Effect of the rule.* The plan may continue to pay benefits secondary to Medicare under paragraph (b)(4)(i) of this section. However, the plan may not differentiate in the services covered and the payments made between persons who have ESRD and those who do not.

(c) *Examples.* (1) (Rule (b)(1).) Mr. A, who is covered by a GHP, became entitled to Medicare on the basis of ESRD in January 1992. On December 20, 1992, Mr. A attained age 65 and became entitled on the basis of age. Since prior law was still in effect (OBRA '93 amendment was effective in August 1993), Medicare became primary payer as of December 1992, when dual entitlement began.

(2) (Rule (b)(2).) Miss B, who has GHP coverage, became entitled to Medicare on the basis of ESRD in July 1992, and also entitled on the basis of disability in June 1993. Medicare was primary payer from June 1993 through August 9, 1993, because the plan permissibly took into account the ESRD-based entitlement (ESRD was not the ''sole'' basis of Medicare entitlement); secondary payer from August 10, 1993, through December 1993, the 18th month of ESRD-based entitlement (the plan is no longer permitted to take into account ESRD-based entitlement that is not the ''sole'' basis of Medicare entitlement); and again became primary payer beginning January 1994.

(3) (Rule (b)(3).) Mr. C, who is 67 years old and entitled to Medicare on the basis of age, has GHP coverage by virtue of current employment status. Mr. C is diagnosed as having ESRD and begins a course of maintenance dialysis on June 27, 1993. Effective September 1, 1993, Mr. C. is eligible for Medicare on the basis of ESRD. Medicare, which was secondary because Mr. C's GHP coverage was by virtue of current employment, continues to be secondary payer through February 1995, the 18th month of ESRD-based eligibility, and becomes primary payer beginning March 1995.

(4) (Rule (b)(3).) Mr. D retired at age 62 and maintained GHP coverage as a retiree. In January 1994, at the age of 64, Mr. D became entitled to Medicare based on ESRD. Seven months into the 18-month coordination period (July 1994) Mr. D turned age 65. The coordination period continues without regard

to age-based entitlement, with the retirement plan continuing to pay primary benefits through June 1995, the 18th month of ESRD-based entitlement. Thereafter, Medicare becomes the primary payer.

(5) (Rule (b)(3).) Mrs. E retired at age 62 and maintained GHP coverage as a retiree. In July 1994, she simultaneously became eligible for Medicare based on ESRD (maintenance dialysis began in April 1994) and entitled based on age. The retirement plan must pay benefits primary to Medicare from July 1994 through December 1995, the first 18 months of ESRD-based eligibility. Thereafter, Medicare becomes the primary payer.

(6) (Rule (b)(3).) Mr. F, who is 67 years of age, is working and has GHP coverage because of his employment status, subsequently develops ESRD, and begins a course of maintenance dialysis in October 1994. He becomes eligible for Medicare based on ESRD effective January 1, 1995. Under the working aged provision, the plan continues to pay primary to Medicare through December 1994. On January 1, 1995, the working aged provision ceases to apply and the ESRD MSP provision takes effect. In September 1995, Mr. F retires. The GHP must ignore Mr. F's retirement status and continue to pay primary to Medicare through June 1996, the end of the 18-month coordination period.

(7) (Rule (b)(4).) Mrs. G, who is 67 years of age, is retired. She has GHP retirement coverage through her former employer. Her plan permissibly took into account her age-based Medicare entitlement when she retired and is paying benefits secondary to Medicare. Mrs. G subsequently develops ESRD and begins a course of maintenance dialysis in October 1995. She automatically becomes eligible for Medicare based on ESRD effective January 1, 1996. The plan continues to be secondary on the basis of Mrs. G's age-based entitlement as long as the plan does not differentiate in the services it provides to Mrs. G and does not do anything else that would constitute ''taking into account'' her ESRD-based eligibility.

[60 FR 45369, Aug. 31, 1995; 60 FR 53876, Oct. 18, 1995]

§411.165 Basis for conditional Medicare payments.

(a) *General rule*. Except as specified in paragraph (b) of this section, the Medicare intermediary or carrier may make a conditional payment if—

(1) The beneficiary, the provider, or the supplier that has accepted assignment files a proper claim under the group health plan and the plan denies the claim in whole or in part; or

(2) The beneficiary, because of physical or mental incapacity, fails to file a proper claim.

(b) *Exception*. Medicare does not make conditional primary payments under either of the following circumstances:

(1) The claim is denied for one of the following reasons:

(i) It is alleged that the group health plan is secondary to Medicare.

(ii) The group health plan limits its payments when the individual is entitled to Medicare.

(iii) Failure to file a proper claim if that failure is for any reason other than the physical or mental incapacity of the beneficiary.

(2) The group health plan fails to furnish information requested by CMS and necessary to determine whether the employer plan is primary to Medicare.

[57 FR 36015, Aug. 12, 1992. Redesignated and amended at 60 FR 45362, 45370, Aug. 31, 1995; 60 FR 53877, Oct. 18, 1995]

Subpart G—Special Rules: Aged Beneficiaries and Spouses Who Are Also Covered Under Group Health Plans

§411.170 General provisions.

(a) *Basis*. (1) This subpart is based on certain provisions of section 1862(b) of the Act, which impose specific requirements and limitations with respect to—

(i) Individuals who are entitled to Medicare on the basis of age; and

(ii) GHPs of at least one employer of 20 or more employees that cover those individuals.

(2) Under these provisions, the following rules apply:

(i) An employer is considered to employ 20 or more employees if the employer has 20 or more employees for

each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(ii) The plan may not take into account the Medicare entitlement of—

(A) An individual age 65 or older who is covered or seeks to be covered under the plan by virtue of current employment status; or

(B) The spouse, including divorced or common-law spouse age 65 or older of an individual (of any age) who is covered or seeks to be covered by virtue of current employment status. (Section 411.108 gives examples of actions that constitute ''taking into account.'')

(iii) Regardless of whether entitled to Medicare, employees and spouses age 65 or older, including divorced or common-law spouses of employees of any age, are entitled to the same plan benefits under the same conditions as employees and spouses under age 65.

(b) [Reserved]

(c) *Determination of ''aged''*. (1) An individual attains a particular age on the day preceding the anniversary of his or her birth.

(2) The period during which an individual is considered to be ''aged'' begins on the first day of the month in which that individual attains age 65.

(3) For services furnished before May 1986, the period during which an individual is considered ''aged'' ends as follows:

(i) For services furnished before July 18, 1984, it ends on the last day of the month in which the individual attains age 70.

(ii) For services furnished between July 18, 1984 and April 30, 1986, it ends on the last day of the month *before* the month the individual attains age 70.

(4) For services furnished on or after May 1, 1986, the period has no upper age limit.

[54 FR 41734, Oct. 11, 1989. Redesignated and amended at 60 FR 45362, 45370, Aug. 31, 1995]

§ 411.172 Medicare benefits secondary to group health plan benefits.

(a) *Conditions that the individual must meet*. Medicare Part A and Part B benefits are secondary to benefits payable by a GHP for services furnished during any month in which the individual—

(1) Is aged;

(2) Is entitled to Medicare Part A benefits under § 406.10 of this chapter; and

(3) Meets one of the following conditions:

(i) Is covered under a GHP of an employer that has at least 20 employees (including a multi-employer plan in which at least one of the participating employers meets that condition), and coverage under the plan is by virtue of the individual's current employment status.

(ii) Is the aged spouse (including a divorced or common-law spouse) of an individual (of any age) who is covered under a GHP described in paragraph (a)(3)(i) of this section by virtue of the individual's current employment status.

(b) *Special rule for multi-employer plans*. The requirements and limitations of paragraph (a) of this section and of (a)(2)(iii) of § 411.170 do not apply with respect to individuals enrolled in a multi-employer plan if—

(1) The individuals are covered by virtue of current employment status with an employer that has fewer than 20 employees; and

(2) The plan requests an exception and identifies the individuals for whom it requests the exception as meeting the conditions specified in paragraph (b)(1) of this section.

(c) *Refusal to accept group health plan coverage*. An employee or spouse may refuse the health plan offered by the employer. If the employee or spouse refuses the plan—

(1) Medicare is primary payer for that individual; and

(2) The plan may not offer that individual coverage complementary to Medicare.

(d) *Reemployed retiree or annuitant*. A reemployed retiree or annuitant who is covered by a GHP and who performs sufficient services to qualify for coverage on that basis (that is, other employees in the same category are provided health benefits) is considered covered ''by reason of current employment status'' even if:

(1) The employer provides the same GHP coverage to retirees; or

(2) The premiums for the plan are paid from a retirement or pension fund.

(e) *Secondary payments.* Medicare pays secondary benefits, within the limitations specified in §§411.32 and 411.33, to supplement the primary benefits paid by the group health plan if that plan pays only a portion of the charge for the services.

(f) *Disabled aged individuals who are considered employed.* (1) For services furnished on or after November 12, 1985, and before July 17, 1987, a disabled, nonworking individual age 65 or older was considered employed if he or she—

(i) Was receiving, from an employer, disability payments that were subject to tax under the Federal Insurance Contributions Act (FICA); and

(ii) For the month before the month of attainment of age 65, was not entitled to disability benefits under title II of the Act and 20 CFR 404.315 of the SSA regulations.

(2) For services furnished on or after July 17, 1987, an individual is considered employed if he or she receives, from an employer, disability benefits that are subject to tax under FICA, even if he or she was entitled to Social Security disability benefits before attaining age 65.

(g) *Individuals entitled to Medicare on the basis of age who are also eligible for or entitled to Medicare on the basis of ESRD.* If an aged individual is, or could upon filing an application become, entitled to Medicare on the basis of ESRD, the coordination of benefits rules of subpart F of this part apply.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990. Redesignated and amended at 60 FR 45362, 45370, Aug. 31, 1995; 60 FR 53877, Oct. 18, 1995]

§411.175 Basis for Medicare primary payments.

(a) *General rule.* CMS makes Medicare primary payments for covered services that are—

(1) Furnished to Medicare beneficiaries who have declined to enroll in the GHP;

(2) Not covered by the plan for any individuals or spouses who are enrolled by virtue of the individual's current employment status;

(3) Covered under the plan but not available to particular individuals or spouses enrolled by virtue of current employment status because they have exhausted their benefits under the plan;

(4) Furnished to individuals whose COBRA continuation coverage has been terminated because of the individual's Medicare entitlement; or

(5) Covered under COBRA continuation coverage notwithstanding the individual's Medicare entitlement.

(b) *Conditional Medicare payments: Basic rule.* Except as provided in paragraph (c) of this section, Medicare may make a conditional primary payment if—

(1) The beneficiary, the provider, or the supplier that has accepted assignment has filed a proper claim under the group health plan and the plan has denied the claim in whole or in part; or

(2) The beneficiary, because of physical or mental incapacity, failed to file proper claim.

(c) *Conditional primary payments: Exception.* Medicare does not make conditional primary payments under either of the following circumstances:

(1) The claim is denied for one of the following reasons:

(i) It is alleged that the group health plan is secondary to Medicare.

(ii) The plan limits its payments when the individual is entitled to Medicare.

(iii) The plan covers the services for individuals or spouses who are enrolled in the plan by virtue of current employment status and are under age 65 but not for individuals and spouses who are enrolled on the same basis but are age 65 or older.

(iv) Failure to file a proper claim if that failure is for any reason other than physical or mental incapacity of the beneficiary.

(2) The group health plan fails to furnish information requested by CMS and necessary to determine whether the employer plan is primary to Medicare.

[54 FR 41734, Oct. 11, 1989. Redesignated and amended at 60 FR 45362, 45371, Aug. 31, 1995]

Subpart H—Special Rules: Disabled Beneficiaries Who Are Also Covered Under Large Group Health Plans

SOURCE: 60 FR 45371, Aug. 31, 1995, unless otherwise noted.

§ 411.200 Basis.

(a) This subpart is based on certain provisions of section 1862(b) of the Act, which impose specific requirements and limitations with respect to—

(1) Individuals who are entitled to Medicare on the basis of disability; and

(2) Large group health plans (LGHPs) that cover those individuals.

(b) Under these provisions, the LGHP may not take into account the Medicare entitlement of a disabled individual who is covered (or seeks to be covered) under the plan by virtue of his or her own current employment status or that of a member of his or her family. (§ 411.108 gives examples of actions that constitute taking into account.)

§ 411.201 Definitions.

As used in this subpart—

Entitled to Medicare on the basis of disability means entitled or deemed entitled on the basis of entitlement to social security disability benefits or railroad retirement disability benefits. (§ 406.12 of this chapter explains the requirements an individual must meet in order to be entitled or deemed to be entitled to Medicare on the basis of disability.)

Family member means a person who is enrolled in an LGHP based on another person's enrollment; for example, the enrollment of the named insured individual. Family members may include a spouse (including a divorced or common-law spouse), a natural, adopted, foster, or stepchild, a parent, or a sibling.

§ 411.204 Medicare benefits secondary to LGHP benefits.

(a) Medicare benefits are secondary to benefits payable by an LGHP for services furnished during any month in which the individual—

(1) Is entitled to Medicare Part A benefits under § 406.12 of this chapter;

(2) Is covered under an LGHP; and

(3) Has LGHP coverage by virtue of his or her own or a family member's current employment status.

(b) *Individuals entitled to Medicare on the basis of disability who are also eligible for, or entitled to, Medicare on the basis of ESRD.* If a disabled individual is, or could upon filing an application become, entitled to Medicare on the basis of ESRD, the coordination of benefits rules of subpart F of this part apply.

§ 411.206 Basis for Medicare primary payments and limits on secondary payments.

(a) *General rule.* CMS makes Medicare primary payments for services furnished to disabled beneficiaries covered under the LGHP by virtue of their own or a family member's current employment status if the services are—

(1) Furnished to Medicare beneficiaries who have declined to enroll in the GHP;

(2) Not covered under the plan for the disabled individual or similarly situated individuals;

(3) Covered under the plan but not available to particular disabled individuals because they have exhausted their benefits under the plan;

(4) Furnished to individuals whose COBRA continuation coverage has been terminated because of the individual's Medicare entitlement; or

(5) Covered under COBRA continuation coverage notwithstanding the individual's Medicare entitlement.

(b) *Conditional primary payments: Basic rule.* Except as provided in paragraph (c) of this section, CMS may make a conditional Medicare primary payment for any of the following reasons:

(1) The beneficiary, the provider, or the supplier that has accepted assignment has filed a proper claim with the LGHP and the LGHP has denied the claim in whole or in part.

(2) The beneficiary, because of physical or mental incapacity, failed to file a proper claim.

(c) *Conditional primary payments: Exceptions.* CMS does not make conditional Medicare primary payments if—

(1) The LGHP denies the claim in whole or in part for one of the following reasons:

(i) It is alleged that the LGHP is secondary to Medicare.

(ii) The LGHP limits its payments when the individual is entitled to Medicare.

(iii) The LGHP does not provide the benefits to individuals who are entitled to Medicare on the basis of disability and covered under the plan by virtue of current employment status but does

provide the benefits to other similarly situated individuals enrolled in the plan.

(iv) The LGHP takes into account entitlement to Medicare in any other way.

(v) There was failure to file a proper claim for any reason other than physical or mental incapacity of the beneficiary.

(2) The LGHP, an employer or employee organization, or the beneficiary fails to furnish information that is requested by CMS and that is necessary to determine whether the LGHP is primary to Medicare.

(d) *Limit on secondary payments.* The provisions of §411.172(e) also apply to services furnished to the disabled under this subpart.

Subpart I [Reserved]

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

SOURCE: 69 FR 16126, March 26, 2004, unless otherwise noted.

§411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare Part A or Part B report information concerning ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

§411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

Centralized building means all or part of a building, including, for purposes of this subpart only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider or supplier (for example, a diagnostic imaging facility) is not a centralized building for purposes of this subpart. This provision does not preclude a group practice from providing services to other providers or suppliers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are clinical laboratory services for purposes of this subpart. Any service not specifically identified as a clinical laboratory service on the List of CPT/HCPCS Codes is not

a clinical laboratory service for purposes of this subpart.

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

(1) The physician's opinion or advice regarding evaluation and/or management of a specific medical problem is requested by another physician.

(2) The request and need for the consultation are documented in the patient's medical record.

(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

(1) Clinical laboratory services.

(2) Physical therapy, occupational therapy, and speech-language pathology services.

(3) Radiology and certain other imaging services.

(4) Radiation therapy services and supplies.

(5) Durable medical equipment and supplies.

(6) Parenteral and enteral nutrients, equipment, and supplies.

(7) Prosthetics, orthotics, and prosthetic devices and supplies.

(8) Home health services.

(9) Outpatient prescription drugs.

(10) Inpatient and outpatient hospital services.

Except as otherwise noted in this subpart, the term ''designated health services'' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, ambulatory surgical center services or SNF Part A payments), except to the extent the services listed in paragraphs (1) through (10) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS).

Does not violate the anti-kickback statute, as used in this subpart only, means that the particular arrangement—

(1) Meets a safe harbor under the anti-kickback statute in § 1001.952 of this title, ''Exceptions'';

(2) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (*e.g.*, the entity furnishing DHS) with respect to the particular arrangement (and not a similar arrangement), provided that the arrangement is conducted in accordance with the facts certified by the requesting party and the opinion is otherwise issued in accordance with part 1008 of this title, ''Advisory Opinions by the OIG''; or

(3) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.

A favorable advisory opinion for purposes of this definition means an opinion in which the OIG opines that—

(1) The party's specific arrangement does not implicate the anti-kickback statute, does not constitute prohibited remuneration, or fits in a safe harbor under § 1001.952 of this title; or

(2) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128(a)(7) and 1128a(b)(7) of the Act) in connection with the party's specific arrangement.

Durable medical equipment (DME) and supplies has the meaning given in section 1861(n) of the Act and § 414.202 of this chapter.

Employee means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Entity means—

(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, not-for-profit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it-

(i) Is the person or entity to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf; or

(ii) Is the person or entity to which the right to payment for the DHS has been reassigned pursuant to §424.80(b)(1) (employer), (b)(2) (facility), or (b)(3) (health care delivery system) of this chapter (other than a health care delivery system that is a health plan (as defined in §1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

(2) A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §424.80(b)(1) and (b)(2) of this chapter, with respect to any designated health services provided by that supplier.

(3) For purposes of this subpart, ''entity'' does not include a physician's practice when it bills Medicare for a diagnostic test in accordance with §414.50 of this chapter (Physician billing for purchased diagnostic tests) and section 3060.4 of the Medicare Carriers Manual (Purchased diagnostic tests), as amended or replaced from time to time.

Fair market value means the value in arm's-length transactions, consistent with the general market value. ''General market value'' means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. With respect to rentals and leases described in §411.357(a), (b), and (l) (as to equipment leases only), ''fair market value'' means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

An hourly payment for a physician's personal services (that is, services performed by the physician personally and not by employees, contractors, or others) shall be considered to be fair market value if the hourly payment is established using either of the following two methodologies:

(1) The hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market.

(2) The hourly rate is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in at least

four of the following surveys and dividing by 2,000 hours. The surveys are:

• Sullivan, Cotter & Associates, Inc.—Physician Compensation and Productivity Survey

• Hay Group—Physicians Compensation Survey

• Hospital and Healthcare Compensation Services—Physician Salary Survey Report

• Medical Group Management Association—Physician Compensation and Productivity Survey

• ECS Watson Wyatt—Hospital and Health Care Management Compensation Report

• William M. Mercer—Integrated Health Networks Compensation Survey

Home health services means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter.

Hospital means any entity that qualifies as a ''hospital'' under section 1861(e) of the Act, as a ''psychiatric hospital'' under section 1861(f) of the Act, or as a ''critical access hospital'' under section 1861(mm)(1) of the Act, and refers to any separate legally organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a ''hospital'' does not include entities that perform services for hospital patients ''under arrangements'' with the hospital.

HPSA means, for purposes of this subpart, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

''Incident to'' services means those services that meet the requirements of section 1861(s)(2)(A) of the Act, 42 CFR § 410.26, and section 2050 of the Medicare Carriers (CMS Pub. 14–3), Part 3—Claims Process, as amended or replaced from time to time.

Inpatient hospital services means those services defined in section 1861(b) of the Act and § 409.10(a) and (b) of this chapter and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient critical access hospital services, as defined in section 1861(mm)(2) of the Act. ''Inpatient hospital services'' do not include emergency inpatient services provided by a hospital located outside of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. ''Inpatient hospital services'' also do not include dialysis furnished by a hospital that is not certified to provide end-stage renal dialysis (ESRD) services under subpart U of part 405 of this chapter. ''Inpatient hospital services'' include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. ''Inpatient hospital services'' do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or

both) or only serving as a mailing service and not performing testing are not considered laboratories.

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are designated health services under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually, as published in the FEDERAL REGISTER, and is posted on the CMS Web site at *http://www.cms.gov/medlearn/refphys.asp.*

Locum tenens physician means a physician who substitutes (that is, ''stands in the shoes'') in exigent circumstances for a physician, in accordance with applicable reassignment rules and regulations, including section 3060.7 of the Medicare Carriers Manual (CMS Pub. 14–3), Part 3—Claims Process, as amended or replaced from time to time.

Member of the group or member of a group practice means, for purposes of this subpart, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes ''patient care services'' to the group as defined in this section. An independent contractor or a leased employee is not a member of the group (unless the leased employee meets the definition of an ''employee'' under this §411.351).

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (s)(2)(C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient critical access hospital services, as defined in section 1861(mm)(3) of the Act. ''Outpatient hospital services'' do not include emergency services furnished by nonparticipating hospitals and covered under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. ''Outpatient hospital services'' include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. ''Outpatient hospital services'' do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Outpatient prescription drugs mean all drugs covered by Medicare Part B or Part D.

Parenteral and enteral nutrients, equipment, and supplies means the following services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies,* meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (CMS Pub. 6), as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies,* meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (CMS Pub. 6), as amended or replaced from time to time.

Patient care services means any task(s) performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters

or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

Physical therapy, occupational therapy, and speech-language pathology services means those particular services so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are physical therapy, occupational therapy, and speech-language pathology services for purposes of this subpart. Any service not specifically identified as physical therapy, occupational therapy or speech-language pathology on the List of CPT/HCPCS Codes is not a physical therapy, occupational therapy, or speech-language pathology service for purposes of this subpart. The list of codes identifying physical therapy, occupational therapy, and speech-language pathology services for purposes of this regulation includes the following:

(1) *Physical therapy services,* meaning those outpatient physical therapy services (including speech-language pathology services) described at section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment;

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been reached; however, maintenance therapy itself is not covered as part of these services; or

(iv) Speech-language pathology services that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

(2) *Occupational therapy services,* meaning those services described at section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;

(ii) Evaluation of an individual's level of independent functioning;

(iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or

(iv) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract must fit in the personal services exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules at § 424.80(b)(3) of this chapter (see also section 3060.3 of the Medicare Carriers Manual (CMS Pub. 14–3), Part 3—Claims Process, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

Physician incentive plan means any compensation arrangement between an entity (or downstream subcontractor)

and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of services.

Professional courtesy means the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these items and services that are covered by Medicare):

(1) *Orthotics*, meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) *Prosthetics*, meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) *Prosthetic devices*, meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(4) *Prosthetic supplies*, meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies so identified on the List of CPT/HCPCS Codes. All services and supplies so identified on the List of CPT/HCPCS Codes are radiation therapy services and supplies for purposes of this subpart. Any service or supply not specifically identified as radiation therapy services or supplies on the List of CPT/HCPCS Codes is not a radiation therapy service or supply for purposes of this subpart. The list of codes identifying radiation therapy services and supplies is based on section 1861(s)(4) of the Act and §410.35 of this chapter, but does not include nuclear medicine procedures.

Radiology and certain other imaging services means those particular services so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are radiology and certain other imaging services for purposes of this subpart. Any service not specifically identified as radiology and certain other imaging services on the List of CPT/HCPCS Codes, is not a radiology or certain other imaging service for purposes of this subpart. The list of codes identifying radiology and certain other imaging services includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, or other imaging services, computerized axial tomography, or magnetic resonance imaging, as covered under section 1861(s)(3) of the Act and §410.32 and §410.34 of this chapter but does not include—

(1) X-ray , fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(2) Radiology procedures that are integral to the performance of a nonradiological medical procedure and performed—

(i) During the nonradiological medical procedure; or

(ii) Immediately following the nonradiological medical procedure when necessary to confirm placement of an item placed during the nonradiological medical procedure; and

(3) Diagnostic nuclear medicine procedures.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or

provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy, if—

(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity. A referring physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity.

(3) A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the plan (or a subcontractor of the insurer or plan) and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior loading docks or parking garages. For purposes of this section, the ''same building'' does not include a mobile vehicle, van, or trailer.

Specialty hospital means a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that is primarily or exclusively engaged in the care and treatment of one of the following: Patients with a cardiac condition; patients with an orthopedic condition; patients receiving a surgical procedure; or any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital. A ''specialty hospital'' does not include any hospital—

(1) Determined by the Secretary to be in operation before or under development as of November 18, 2003;

(2) For which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(3) For which the type of categories described above is no different at any time on or after such date than the type of such categories as of such date;

(4) For which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(5) that meets such other requirements as the Secretary may specify.

Transaction means an instance or process of two or more persons or entities doing business. An isolated transaction means one involving a single payment between two or more persons or entities or a transaction that involves integrally related installment payments provided that—

(1) The total aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician; and

(2) The payments are immediately negotiable or are guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to assure payment even in the event of default by the purchaser or obligated party. § 411.352 Group practice.

[69 FR 16126, March 26, 2004, as amended at 70 FR 4525, Jan. 28, 2005]

411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity*. The group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, not-for-profit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this subpart, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a single legal entity may itself own subsidiary entities. A group practice operating in more than one State will be considered to be a single legal entity notwithstanding that it is composed of multiple legal entities, provided that—

(1) The States in which the group practice is operating are contiguous (although each State need not be contiguous to every other State);

(2) The legal entities are absolutely identical as to ownership, governance, and operation; and

(3) Organization of the group practice into multiple entities is necessary to comply with jurisdictional licensing laws of the States in which the group practice operates.

(b) *Physicians.* The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined in § 411.351.

(c) *Range of care.* Each physician who is a member of the group, as defined in § 411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) *Services furnished by group practice members.* (1) Except as otherwise provided in paragraphs (d)(3), (d)(4), (d)(5), and (d)(6) of this section, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. ''Patient care services'' must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30 hours a week on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this ''substantially all test'' and related supportive documentation must be made available to the Secretary upon request.

(3) The ''substantially all test'' set forth in paragraph (d)(1) of this section does not apply to any group practice that is located solely in an HPSA, as defined in § 411.351.

(4) For a group practice located outside of an HPSA (as defined in § 411.351), any time spent by a group practice member providing services in an HPSA should not be used to calculate whether the group practice has met the ''substantially all test,'' regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the ''start up'' period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the ''substantially all'' test requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or reorganizes.

(6)(i) If the addition to an existing group practice of a new member who would be considered to have relocated his or her practice under § 411.457(e)(2) would result in the existing group practice not meeting the ''substantially all'' test set forth in paragraph (d)(1) of this section, the group practice will have 12 months following the addition of the new member to come back into full compliance, provided that—

(A) For the 12-month period the group practice is fully compliant with the ''substantially all'' test if the new member is not counted as a member of the group for purposes of § 411.352; and

(B) The new member's employment with, or ownership interest in, the group practice is documented in writing no later than the beginning of his or her new employment, ownership, or investment.

(ii) This paragraph (d)(6) does not apply when an existing group practice reorganizes or admits a new member who is not relocating his or her practice.

(e) *Distribution of expenses and income.* The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this section prevents a group practice from adjusting its compensation methodology prospectively,

subject to restrictions on the distribution of revenue from DHS under §411.352(i).

(f) *Unified business.* (1) The group practice must be a unified business having at least the following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and

(ii) Consolidated billing, accounting, and financial reporting.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under §411.352(i).

(g) *Volume or value of referrals.* No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of referrals by the physician, except as provided in §411.352(i).

(h) *Physician-patient encounters.* Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) *Special rule for productivity bonuses and profit shares.* (1) A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services that he or she has personally performed (including services ''incident to'' those personally performed services as defined in §411.351), provided that the share or bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.

(2) Overall profits means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. Overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. The share of overall profits will be deemed *not* to relate directly to the volume or value of referrals if *one* of the following conditions is met:

(i) The group's profits are divided per capita (for example, per member of the group or per physician in the group).

(ii) Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group.

(3) A productivity bonus should be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS if one of the following conditions is met:

(i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). (The methodology for establishing RVUs is set forth in §414.22 of this chapter.)

(ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice.

(4) Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

§411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has

an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff; however, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician, if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing*. An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment*. Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

(d) *Refunds*. An entity that collects payment for a designated health service that was performed under a prohibited referral must refund all collected amounts on a timely basis, as defined in § 1003.101 of this title.

(e) *Exception for certain entities*. Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal and State laws, rules, and regulations.

(f) *Exception for certain arrangements involving temporary noncompliance*. (1) Except as provided in paragraphs (f)(2), (f)(3), and (f)(4) of this section, an entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under § 411.355, § 411.356, or § 411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception;

(ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance; and

(iii) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), and the claim or bill otherwise complies with all applicable Federal and State laws, rules, and regulations.

(2) Paragraph (f)(1) of this section applies only to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception.

(3) This paragraph (f) may only be used by an entity once every 3 years with respect to the same referring physician.

(4) This paragraph (f) does not apply if the exception with which the financial relationship previously complied was § 411.357(k) or (m).

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships*. (1) *Financial relationship means*—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his

or her immediate family) and the entity furnishing DHS without any intervening persons or entities. (3) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, stock options other than those described in §411.354(b)(3)(ii), partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in a retirement plan;

(ii) Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to equity (before this time the stock options or convertible securities are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section); or

(iv) An ''under arrangements'' contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS ''under arrangements'' with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section).

(4) An ownership or investment interest that meets an exception set forth in §411.355 or §411.356 need not also meet an exception for compensation arrangements set forth in §411.357 with respect to profit distributions, dividends, or interest payments on secured obligations.

(5) *Indirect ownership or investment interest.* (i) An indirect ownership or investment interest exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) An indirect ownership or investment interest exists even though the entity furnishing DHS does not know, or act in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(iii) Notwithstanding anything in this paragraph (b)(5), common ownership or investment in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor.

(iv) An indirect ownership or investment interest requires an unbroken chain of ownership interests between the referring physician and the entity furnishing DHS such that the referring physician has an indirect ownership or investment interest *in* the entity furnishing DHS.

(c) *Compensation arrangement.* A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An ''under arrangements'' contract between a hospital and an entity providing DHS ''under arrangements'' to the hospital

creates a compensation arrangement for purposes of these regulations.

(1) A compensation arrangement does not include the portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term ''remuneration'' in § 411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(2) *Indirect compensation arrangement.* An *indirect* compensation arrangement exists if—

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under § 411.354(d)(2) or (d)(3). If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and subpart J of this part.

(1) Compensation will be considered ''set in advance'' if the aggregate compensation, a time-based or per unit of service based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that reflects the volume or value of referrals or other business generated by the referring physician.

(2) Unit-based compensation (including time-based or per unit of service based compensation) will be deemed not to take into account ''the volume or value of referrals'' if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS.

(3) Unit-based compensation (including time-based or per unit of service based compensation) will be deemed to not take into account ''other business generated between the parties'' so long as the compensation is fair market value for items and services actually provided and does not vary during the

course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which will not be considered ''other business generated'' by the referring physician).

(4) A physician's compensation from a *bona fide* employer or under a managed care or other contract may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, so long as the compensation arrangement—

(i) Is set in advance for the term of the agreement;

(ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals);

(iii) Otherwise complies with an applicable exception under §411.355 or §411.357;

(iv) Complies with the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set forth in a written agreement signed by the parties;

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment; and

(v) The required referrals relate solely to the physician's services covered by the scope of the employment or the contract and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation relationship. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment or contract. §411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

§411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in §411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined in §410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined in §411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of paragraph (a) of this section, sbull; physician services'' include only those ''incident to'' services (as defined in §411.351) that are physician services under §410.20(a) of this chapter.

(3) All other ''incident to'' services (for example, diagnostic tests, physical therapy) are outside the scope of paragraph (a) of this section.

(b) *In-office ancillary services.* Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN)), that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) An individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided the supervision complies

with all other applicable Medicare payment and coverage rules for the services.

(2) They are furnished in one of the following locations:

(i) The same building (as defined in § 411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), *or* (b)(2)(i)(C) of this section are satisfied:

(A)(*1*) The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; *and*

(*2*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(B)(*1*) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; *and*

(*3*) The referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(C)(*1*) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section *or* the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section;

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(*3*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

(ii) A centralized building (as defined in § 411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined in § 411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a ''physician in the group practice'' (as defined at § 411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (b)(3)(iv) of this section under a billing number assigned to the physician, group practice, or entity, provided the billing arrangement meets the requirements of § 424.80(b)(6) of this chapter. For purposes of this paragraph (b)(3), a

group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) For purposes of paragraph (b) of this section, DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purposes of ambulating, uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the ''same building'' requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards located in §424.57(c) of this chapter.

(v) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(vi) All other requirements of the in-office ancillary services exception in paragraph (b) of this section are met.

(5) A designated health service is ''furnished'' for purposes of paragraph (b) of this section in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the ''same building'' requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section only, a private home does not include a nursing, long-term care, or other facility or institution, except that a patient may have a private home in an assisted living or independent living facility.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M of this chapter.

(2) A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(6) A managed care organization (MCO) contracting with a State under section 1903(m) of the Act.

(7) A prepaid inpatient health plan (PIHP) or prepaid ambulance health

plan (PAHP) contracting with a State under part 438 of this chapter.

(8) A health insuring organization (HIO) contracting with a State under part 438, subpart D of this chapter.

(9) An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

(d) [Reserved]

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. (A ''component'' of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;

(B) Is licensed to practice medicine in the State(s) in which he or she practices medicine;

(C) Has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital; and

(D) Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph (e)(1)(i)(D).

(ii) The total compensation paid by all academic medical center components to the referring physician is set in advance and, in the aggregate, does not exceed fair market value for the services provided, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center.

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in written agreement(s) or other written document(s) that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant.

(iv) The referring physician's compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) The ''academic medical center'' for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital (as defined at § 411.355(e)(3));

(ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and

(iii) One or more affiliated hospital(s) in which a majority of the physicians

on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions are made by physicians who are faculty members. The hospital for purposes of this paragraph (e)(2)(iii) may be the same hospital that satisfies the requirement of paragraph (e)(2)(i) of this section. For purposes of this provision, a faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. In meeting this paragraph (e)(2)(iii), faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals need not be counted. Any faculty member may be counted, including courtesy and volunteer faculty.

(3) An accredited academic hospital for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs.

(f) *Implants furnished by an ASC*. Implants furnished by an ASC, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices, and implanted DME that meet the following conditions:

(1) The implant is implanted by the referring physician or a member of the referring physician's group practice in a Medicare-certified ASC (under part 416 of this chapter) with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure under §416.65.

(3) The arrangement for the furnishing of the implant does not violate the anti-kickback statute (section 1128B(b) of the Act).

(4) All billing and claims submission for the implants does not violate any Federal or State law or regulation governing billing or claims submission.

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to, and implanted in, the patient.

(g) *EPO and other dialysis-related drugs furnished in or by an ESRD facility*. EPO and other dialysis-related drugs that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph (g): ''EPO and other dialysis-related drugs'' means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and ''furnished'' means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility, or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.

(2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the EPO and other dialysis-related drugs does not violate any Federal or State law or regulation governing billing or claims submission.

(4) The exception set forth in this paragraph (g) does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests, immunizations, and vaccines*. Preventive screening tests, immunizations, and vaccines that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated frequency limits.

(2) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the preventive screening tests, immunizations, and vaccines does not violate any Federal or State law or regulation governing billing or claims submission.

(4) The preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed as eligible for this exception on the List of CPT/HCPCS Codes.

(i) *Eyeglasses and contact lenses following cataract surgery*. Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in § 410.36(a)(2)(ii) and § 414.228 of this chapter, respectively.

(2) The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the eyeglasses or contact lenses does not violate any Federal or State law or regulation governing billing or claims submission.

(j) *Intra-family rural referrals*. (1) Services provided pursuant to a referral from a referring physician to his or her immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if all of the following conditions are met:

(i) The patient who is referred resides in a rural area as defined in § 411.356(c)(1);

(ii) Except as provided in paragraph (j)(1)(iii) of this section, no other person or entity is available to furnish the services in a timely manner in light of the patient's condition within 25 miles of the patient's residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or in-home DME), no other person or entity is available to furnish the services in a timely manner in light of the patient's condition; and

(iv) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission;

(2) The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles from the patient's residence.

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly-traded securities*. Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

(2) They are in a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. ''Stockholder equity'' is the difference in value between a corporation's total assets and total liabilities.

(b) *Mutual funds*. Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities, for purposes of the services specified:

(1) A rural provider, in the case of DHS furnished in a rural area by the provider. A ''rural provider'' is an entity that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area and, for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), is not a specialty hospital. A rural area for purposes of this paragraph (c)(1) is an area that is not an urban area as defined in §412.62(f)(1)(ii) of this chapter.

(2) A hospital that is located in Puerto Rico, in the case of DHS furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if—

(i) the referring physician is authorized to perform services at the hospital;

(ii) effective for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), the hospital is not a specialty hospital; and

(iii) the ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

§411.357 Exceptions to the referral prohibition related to compensation arrangements.

For purposes of §411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The term of the agreement is at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the agreement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the agreement are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) A holdover month-to-month rental for up to 6 months immediately following an agreement of at least 1 year that met the conditions of this paragraph (a) will satisfy this paragraph (a), provided the holdover rental is on the same terms and conditions as the immediately preceding agreement.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee and is not shared with or used by the lessor or any person or entity related to the lessor.

(3) The agreement provides for a term of rental or lease of at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may

not enter into a new agreement during the first year of the original term of the agreement.

(4) The rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(5) The agreement would be commercially reasonable even if no referrals were made between the parties.

(6) A holdover month-to-month rental for up to 6 months immediately following an agreement of at least 1 year that met the conditions of this paragraph (b) will satisfy this paragraph (b), provided the holdover rental is on the same terms and conditions as the immediately preceding agreement.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a *bona fide* employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(d) *Personal service arrangements. (1) General*—Remuneration from an entity under an arrangement or multiple arrangements to a physician, an immediate family member of the physician, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement will be met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of contracts. A physician or family member can ''furnish'' services through employees whom they have hired for the purpose of performing the services; through a wholly owned entity; or through *locum tenens* physicians (as defined in § 411.351, except that the regular physician need not be a member of a group practice).

(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The term of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated during the term with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement.

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined in § 411.351) between a

physician and an entity (or downstream subcontractor), the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.

(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream subcontractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined in §422.208, the entity (and/or any downstream contractor) complies with the requirements concerning physician incentive plans set forth at §422.208 and §422.210 of this chapter.

(e) *Physician recruitment.* (1) Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by both parties;

(ii) The arrangement is not conditioned on the physician's referral of patients to the hospital;

(iii) The hospital does not determine (directly or indirectly) the amount of the remuneration to the physician based on the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under a separate employment or services contract that complies with §411.354(d)(4)).

(2) The ''geographic area served by the hospital'' is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. A physician will be considered to have relocated his or her medical practice if—

(i) The physician moves his or her medical practice at least 25 miles; or

(ii) The physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year). For the initial ''start up'' year of the recruited physician's practice, the 75 percent test in the preceding sentence will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

(3) Residents and physicians who have been in practice 1 year or less will not be subject to the relocation requirement of this paragraph, except that the recruited resident or physician must establish his or her medical practice in the geographic area served by the hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician or physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

(i) The written agreement in §411.357(e)(1) is also signed by the party to whom the payments are directly made;

(ii) Except for actual costs incurred by the physician or physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician;

(iii) In the case of an income guarantee made by the hospital to a recruited physician who joins a physician or physician practice, the costs allocated by the physician or physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician;

(iv) Records of the actual costs and the passed through amounts are maintained for a period of at least 5 years and made available to the Secretary upon request;

(v) The remuneration from the hospital under the arrangement is not to be determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital;

(vi) The physician or physician practice may not impose additional practice restrictions on the recruited physician other than conditions related to quality of care; and

(vii) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(5) This paragraph (e) applies to remuneration provided by a federally qualified health center in the same manner as it applies to remuneration provided by a hospital, so long as the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the following conditions are met:

(1) The amount of remuneration under the isolated transaction is—

(i) Consistent with the fair market value of the transaction; and

(ii) Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties.

(2) The remuneration is provided under an agreement that would be commercially reasonable even if the physician made no referrals.

(3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in § 411.355 through § 411.357 and except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician.

(g) *Certain arrangements with hospitals.* Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as ''unrelated,'' remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. Remuneration relates to the furnishing of DHS if it—

(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;

(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or

(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services furnished to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before, and has continued in effect without interruption since, December 19, 1989.

(3) With respect to the DHS covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(i) *Payments by a physician.* Payments made by a physician (or his or her immediate family member)—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services that are furnished at a price that is consistent with fair market value, and that are not specifically excepted under another provision in §411.355 through §411.357 (including, but not limited to, §411.357(l)). ''Services'' in this context means services of any kind (not just those defined as ''services'' for purposes of the Medicare program in §400.202).

(j) *Charitable donations by a physician. Bona fide* charitable donations made by a physician (or immediate family member) to an entity if all of the following conditions are satisfied:

(1) The charitable donation is made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization);

(2) The donation is neither solicited, nor made, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity; and

(3) The donation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(k) *Non-monetary compensation up to $300.* (1) Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of $300 per year, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(ii) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(iii) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission.

(2) The $300 limit in this paragraph (k) will be adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index-Urban All Items (CPI-U) for the 12–month period ending the preceding September 30. CMS intends to display as soon as possible after September 30 each year, both the increase in the CPI-U for the 12–month period and the new non-monetary compensation limit on the physician self-referral Web site: *http://cms.hhs.gov/medlearn/refphys.asp.*

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in §411.352) for the provision of items or services by the physician (or an immediate family member) or group of physicians to the entity, if the arrangement is set forth in an agreement that meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during

the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

(3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(4) The arrangement would be commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) It does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a State or Federal law.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is provided to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) without regard to the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital Web site or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, Internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital Web site or in hospital advertising, will meet the ''on campus'' requirement of this paragraph (m).

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value). The $25 limit in this paragraph (m)(5) will be adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index-Urban All Items (CPI-U) for the 12–month period ending the preceding September 30. CMS intends to display as soon as possible after September 30 each year both the increase in the CPI-U for the 12–month period and the new limits on the physician self-referral Web site: *http://cms.hhs.gov/medlearn/refphys.asp*.

(6) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The compensation arrangement does not violate the anti-kickback statute, (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(8) Other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have *bona fide* medical staffs may provide compensation under this paragraph (m) on the same terms and conditions applied to hospitals under this paragraph (m).

(n) *Risk-sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians'

association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. For purposes of this paragraph (n), ''health plan'' and ''enrollees'' have the meanings ascribed to those terms in §1001.952(l) of this title.

(o) *Compliance training*. Compliance training provided by an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area, provided the training is held in the local community or service area. For purposes of this paragraph (o), ''compliance training'' means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, reporting); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements); or training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided (but not including continuing medical education).

(p) *Indirect compensation arrangements*. Indirect compensation arrangements, as defined in §411.354(c)(2), if all of the following conditions are satisfied:

(1) The compensation received by the referring physician (or immediate family member) described in §411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

(2) The compensation arrangement described in §411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(q) *Referral services*. Remuneration that meets all of the conditions set forth in §1001.952(f) of this title.

(r) *Obstetrical malpractice insurance subsidies*. Remuneration to the referring physician that meets all of the conditions set forth in §1001.952(o) of this title.

(s) *Professional courtesy*. Professional courtesy (as defined in §411.351) offered by an entity to a physician or a physician's immediate family member or office staff if all of the following conditions are met:

(1) The professional courtesy is offered to all physicians on the entity's *bona fide* medical staff or in the entity's local community or service area without regard to the volume or value of referrals or other business generated between the parties;

(2) The health care items and services provided are of a type routinely provided by the entity;

(3) The entity's professional courtesy policy is set out in writing and approved in advance by the entity's governing body;

(4) The professional courtesy is not offered to a physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need;

(5) If the professional courtesy involves any whole or partial reduction of any coinsurance obligation, the insurer is informed in writing of the reduction; and

(6) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(t) *Retention payments in underserved areas*. (1) Remuneration provided by a hospital or federally qualified health center directly to a physician on the hospital's or federally qualified health

center's medical staff to retain the physician's medical practice in the geographic area served by the hospital or federally qualified health center (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) Paragraphs 411.357(e)(1)(i) through 411.357(e)(1)(iv) are satisfied;

(ii) The geographic area served by the hospital or federally qualified health center is a HPSA (regardless of the physician's specialty) or is an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion issued according to section 1877(g)(6) of the Act;

(iii) The physician has a *bona fide* firm, written recruitment offer from a hospital or federally qualified health center that is not related to the hospital or the federally qualified health center making the payment, and the offer specifies the remuneration being offered and would require the physician to move the location of his or her practice at least 25 miles *and* outside of the geographic area served by the hospital or federally qualified health center making the retention payment;

(iv) The retention payment is limited to the lower of—

(A) The amount obtained by subtracting (1) the physician's current income from physician and related services from (2) the income the physician would receive from comparable physician and related services in the *bona fide* recruitment offer, provided that the respective incomes are determined using a reasonable and consistent methodology, and that they are calculated uniformly over no more than a 24-month period; or

(B) The reasonable costs the hospital or federally qualified health center would otherwise have to expend to recruit a new physician to the geographic area served by the hospital or federally qualified health center in order to join the medical staff of the hospital or federally qualified health center to replace the retained physician;

(v) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the *bona fide* recruitment offer;

(vi) The hospital or federally qualified health center does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years and the amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(vii) The arrangement otherwise complies with all of the conditions of this section; and

(viii) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) The Secretary may waive the relocation requirement of paragraph (t)(1) of this section for payments made to physicians practicing in a HPSA or an area with demonstrated need for the physician through an advisory opinion issued according to section 1877(g)(6) of the Act, if the retention payment arrangement otherwise complies with all of the conditions of this paragraph.

(u) *Community-wide health information systems.* Items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that—

(1) The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(2) The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

(3) The arrangement does not violate the anti-kickback statute, (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

§411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing services for which payment may be made under Medicare must submit information to CMS or to the Office of Inspector General (OIG) concerning their reportable financial relationships (as defined in paragraph (d) of this section), in the form, manner, and at the times that CMS or OIG specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that furnish 20 or fewer Part A and Part B services during a calendar year, or to any Medicare covered services furnished outside the United States.

(c) *Required information.* The information requested by CMS or OIG can include the following:

(1) The name and unique physician identification number (UPIN) of each physician who has a reportable financial relationship with the entity.

(2) The name and UPIN of each physician who has an immediate family member (as defined in §411.351) who has a reportable financial relationship with the entity.

(3) The covered services furnished by the entity.

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with the rules of the Internal Revenue Service and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

(d) *Reportable financial relationships.* For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined in §411.354(b) or any compensation arrangement, as defined in §411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in §411.356(a) or §411.356(b) regarding publicly-traded securities and mutual funds.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information, upon request, within the time period specified by the request. Entities are given at least 30 days from the date of the request to provide the information. Entities must retain the information, and documentation sufficient to verify the information, for the length of time specified by the applicable regulatory requirements for the information, and, upon request, must make that information and documentation available to CMS or OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to $10,000 for each day following the deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to CMS or OIG under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

§411.370 Advisory opinions relating to physician referrals.

(a) *Period during which CMS will accept requests.* The provisions of §411.370 through §411.389 apply to requests for advisory opinions that are submitted to CMS after November 3, 1997, and before August 21, 2000, and to any requests submitted during any other time period during which CMS is required by law to issue the advisory opinions described in this subpart.

(b) *Matters that qualify for advisory opinions and who may request one.* Any individual or entity may request a written advisory opinion from CMS

concerning whether a physician's referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. In the advisory opinion, CMS determines whether a business arrangement described by the parties to that arrangement appears to constitute a ''financial relationship'' (as defined in section 1877(a)(2) of the Act) that could potentially restrict a physician's referrals, and whether the arrangement or the designated health services at issue appear to qualify for any of the exceptions to the referral prohibition described in section 1877 of the Act.

(1) The request must involve an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. CMS does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties.

(2) The requestor must be a party to the existing or proposed arrangement.

(c) *Matters not subject to advisory opinions.* CMS does not address through the advisory opinion process—

(1) Whether the fair market value was, or will be, paid or received for any goods, services, or property; and

(2) Whether an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(d) *Facts subject to advisory opinions.* CMS considers requests for advisory opinions that involve applying specific facts to the subject matter described in paragraph (b) of this section. Requestors must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in § 411.372.

(e) *Requests that will not be accepted.* CMS does not accept an advisory opinion request or issue an advisory opinion if—

(1) The request is not related to a named individual or entity;

(2) CMS is aware that the same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry.

(f) *Effects of an advisory opinion on other Governmental authority.* Nothing in this part limits the investigatory or prosecutorial authority of the OIG, the Department of Justice, or any other agency of the Government. In addition, in connection with any request for an advisory opinion, CMS, the OIG, or the Department of Justice may conduct whatever independent investigation it believes appropriate.

[69 FR 57227, Sept. 24, 2004]

§ 411.372 Procedure for submitting a request.

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to CMS in writing, including an original request and 2 copies. The request must be addressed to: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Office of Financial Management, Division of Premium Billing and Collections, Mail Stop C3–09–27, Attention: Advisory Opinions, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(b) *Information CMS requires with all submissions.* The request must include the following:

(1) The name, address, telephone number, and Taxpayer Identification Number of the requestor.

(2) The names and addresses, to the extent known, of all other actual and potential parties to the arrangement that is the subject of the request.

(3) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the requestor.

(4) A complete and specific description of all relevant information bearing on the arrangement, including—

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including: the purpose of the arrangement;

the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved) and any entities that provide designated health services; the types of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients;

(ii) Complete copies of all relevant documents or relevant portions of documents that affect or could affect the arrangement, such as personal services or employment contracts, leases, deeds, pension or insurance plans, financial statements, or stock certificates (or, if these relevant documents do not yet exist, a complete description, to the best of the requestor's knowledge, of what these documents are likely to contain);

(iii) Detailed statements of all collateral or oral understandings, if any; and

(iv) Descriptions of any other arrangements or relationships that could affect CMS's analysis.

(5) Complete information on the identity of all entities involved either directly or indirectly in the arrangement, including their names, addresses, legal form, ownership structure, nature of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect, and as defined in section 1877(a)(2) of the Act and §411.351), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) A discussion of the specific issues or questions the requestor would like CMS to address including, if possible, a description of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions to the prohibition the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

(7) An indication of whether the parties involved in the request have also asked for or are planning to ask for an advisory opinion on the arrangement in question from the OIG under section 1128D(b) of the Act (42 U.S.C. 1320a–7d(b)) and whether the arrangement is or is not, to the best of the requestor's knowledge, the subject of an investigation.

(8) The certification(s) described in §411.373. The certification(s) must be signed by—

(i) The requestor, if the requestor is an individual;

(ii) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(iii) The managing partner of the requestor, if the requestor is a partnership; or

(iv) A managing member, if the requestor is a limited liability company.

(9) A check or money order payable to CMS in the amount described in §411.375(a).

(c) *Additional information CMS might require.* If the request does not contain all of the information required by paragraph (b) of this section, or, if either before or after accepting the request, CMS believes it needs more information in order to render an advisory opinion, it may request whatever additional information or documents it deems necessary. Additional information must be provided in writing, signed by the same person who signed the initial request (or by an individual in a comparable position), and be certified as described in §411.373.

[69 FR 57227, Sept. 24, 2004]

§411.373 Certification.

(a) Every request must include the following signed certification: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all

of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.''

(b) If the advisory opinion relates to a proposed arrangement, in addition to the certification required by paragraph (a) of this section, the following certification must be included and signed by the requestor: ''The arrangement described in this request for an advisory opinion is one into which [the requestor], in good faith, plans to enter.'' This statement may be made contingent on a favorable advisory opinion, in which case the requestor should add one of the following phrases to the certification:

(1) ''if CMS issues a favorable advisory opinion.''

(2) ''if CMS and the OIG issue favorable advisory opinions.''

[69 FR 57227, Sept. 24, 2004]

§ 411.375 Fees for the cost of advisory opinions.

(a) *Initial payment.* Parties must include with each request for an advisory opinion submitted through December 31, 1998, a check or money order payable to CMS for $250. For requests submitted after this date, parties must include a check or money order in this amount, unless CMS has revised the amount of the initial fee in a program issuance, in which case, the requestor must include the revised amount. This initial payment is nonrefundable.

(b) *How costs are calculated.* Before issuing the advisory opinion, CMS calculates the costs the Department has incurred in responding to the request. The calculation includes the costs of salaries, benefits, and overhead for analysts, attorneys, and others who have worked on the request, as well as administrative and supervisory support for these individuals.

(c) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (c)(3) of this section, to pay all costs the Department incurs in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If CMS estimates that the costs of processing the advisory opinion request have reached or are likely to exceed the designated triggering dollar amount, CMS notifies the requestor.

(3) If CMS notifies the requestor that the actual or estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, CMS stops processing the request until the requestor makes a written request for CMS to continue. If CMS is delayed in processing the request for an advisory opinion because of this procedure, the time within which CMS must issue an advisory opinion is suspended until the requestor asks CMS to continue working on the request.

(4) If the requestor chooses not to pay for CMS to complete an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs CMS has identified as costs it incurred in processing the request for an advisory opinion, up to that point.

(5) If the costs CMS has incurred in responding to the request are greater than the amount the requestor has paid, CMS, before issuing the advisory opinion, notifies the requestor of any additional amount that is due. CMS does not issue an advisory opinion until the requestor has paid the full amount that is owed. Once the requestor has paid CMS the total amount due for the costs of processing the request, CMS issues the advisory opinion. The time period CMS has for issuing advisory opinions is suspended from the time CMS notifies the requestor of the amount owed until the time CMS receives full payment.

(d) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in § 411.377.

(2) The time period for issuing an advisory opinion is suspended from the time that CMS notifies the requestor that it needs an outside expert opinion until the time CMS receives that opinion.

[69 FR 57228, Sept. 24, 2004]

§411.377 Expert opinions from outside sources.

(a) CMS may request expert advice from qualified sources if CMS believes that the advice is necessary to respond to a request for an advisory opinion. For example, CMS may require the use of accountants or business experts to assess the structure of a complex business arrangement or to ascertain a physician's or immediate family member's financial relationship with entities that provide designated health services.

(b) If CMS determines that it needs to obtain expert advice in order to issue a requested advisory opinion, CMS notifies the requestor of that fact and provides the identity of the appropriate expert and an estimate of the costs of the expert advice. As indicated in §411.375(d), the requestor must pay the estimated cost of the expert advice.

(c) Once CMS has received payment for the estimated cost of the expert advice, CMS arranges for the expert to provide a prompt review of the issue or issues in question. CMS considers any additional expenses for the expert advice, beyond the estimated amount, as part of the costs CMS has incurred in responding to the request, and the responsibility of the requestor, as described in §411.375(c).

[69 FR 57229, Sept. 24, 2004]

§411.378 Withdrawing a request.

The party requesting an advisory opinion may withdraw the request before CMS issues a formal advisory opinion. This party must submit the withdrawal in writing to the same address as the request, as indicated in §411.372(a). Even if the party withdraws the request, the party must pay the costs the Department has expended in processing the request, as discussed in §411.375. CMS reserves the right to keep any request for an advisory opinion and any accompanying documents and information, and to use them for any governmental purposes permitted by law.

[69 FR 57229, Sept. 24, 2004]

§411.379 When CMS accepts a request.

(a) Upon receiving a request for an advisory opinion, CMS promptly makes an initial determination of whether the request includes all of the information it will need to process the request.

(b) Within 15 working days of receiving the request, CMS—

(1) Formally accepts the request for an advisory opinion;

(2) Notifies the requestor about the additional information it needs; or

(3) Declines to formally accept the request.

(c) If the requestor provides the additional information CMS has requested, or otherwise resubmits the request, CMS processes the resubmission in accordance with paragraphs (a) and (b) of this section as if it were an initial request for an advisory opinion.

(d) Upon accepting the request, CMS notifies the requestor by regular U.S. mail of the date that CMS formally accepted the request.

(e) The 90-day period that CMS has to issue an advisory opinion set forth in §411.380(c) does not begin until CMS has formally accepted the request for an advisory opinion.

[69 FR 57229, Sept. 24, 2004]

§411.380 When CMS issues a formal advisory opinion.

(a) CMS considers an advisory opinion to be issued once it has received payment and once the opinion has been dated, numbered, and signed by an authorized CMS official.

(b) An advisory opinion contains a description of the material facts known to CMS that relate to the arrangement that is the subject of the advisory opinion, and states CMS's opinion about the subject matter of the request based on those facts. If necessary, CMS includes in the advisory opinion material facts that could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) CMS issues an advisory opinion, in accordance with the provisions of this part, within 90 days after it has formally accepted the request for an advisory opinion, or, for requests that CMS determines, in its discretion, involve complex legal issues or highly complicated fact patterns, within a reasonable time period.

(2) If the 90th day falls on a Saturday, Sunday, or Federal holiday, the time period ends at the close of the first

business day following the weekend or holiday;

(3) The 90-day period is suspended from the time CMS'

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in § 411.375(c)(2) until CMS receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until CMS receives the additional information;

(iii) Notifies the requestor of the full amount due until CMS receives payment of this amount; and

(iv) Notifies the requestor of the need for expert advice until CMS receives the expert advice.

(d) After CMS has notified the requestor of the full amount owed and has received full payment of that amount, CMS issues the advisory opinion and promptly mails it to the requestor by regular first class U.S. mail.

[69 FR 57229, Sept. 24, 2004]

§ 411.382 CMS's right to rescind advisory opinions.

Any advice CMS gives in an opinion does not prejudice its right to reconsider the questions involved in the opinion and, if it determines that it is in the public interest, to rescind or revoke the opinion. CMS provides notice to the requestor of its decision to rescind or revoke the opinion so that the requestor and the parties involved in the requestor's arrangement may discontinue any course of action they have taken in accordance with the advisory opinion. CMS does not proceed against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon CMS's advice under this part, provided—

(a) The requestor presented to CMS a full, complete and accurate description of all the relevant facts; and

(b) The parties promptly discontinue the action upon receiving notice that CMS had rescinded or revoked its approval, or discontinue the action within a reasonable ''wind down'' period, as determined by CMS.

[69 FR 57229, Sept. 24, 2004]

§ 411.384 Disclosing advisory opinions and supporting information.

(a) Advisory opinions that CMS issues and releases in accordance with the procedures set forth in this subpart are available to the public.

(b) Promptly after CMS issues an advisory opinion and releases it to the requestor, CMS makes available a copy of the advisory opinion for public inspection during its normal hours of operation and on the DHHS/CMS Web site.

(c) Any predecisional document, or part of such predecisional document, that is prepared by CMS, the Department of Justice, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part is exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to CMS in connection with a request for an advisory opinion are available to the public to the extent they are required to be made available by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section limits CMS's obligation, under applicable laws, to publicly disclose the identity of the requesting party or parties, and the nature of the action CMS has taken in response to the request.

[69 FR 57230, Sept. 24, 2004]

§ 411.386 CMS's advisory opinions as exclusive.

The procedures described in this subpart constitute the only method by which any individuals or entities can obtain a binding advisory opinion on the subject of a physician's referrals, as described in § 411.370. CMS has not and does not issue a binding advisory opinion on the subject matter in § 411.370, in either oral or written form, except through written opinions it issues in accordance with this subpart.

[69 FR 57230, Sept. 24, 2004]

§ 411.387 Parties affected by advisory opinions.

An advisory opinion issued by CMS does not apply in any way to any individual or entity that does not join in

the request for the opinion. Individuals or entities other than the requestor(s) may not rely on an advisory opinion.

[69 FR 57230, Sept. 24, 2004]

§411.388 When advisory opinions are not admissible evidence.

The failure of a party to seek or to receive an advisory opinion may not be introduced into evidence to prove that the party either intended or did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

[69 FR 57230, Sept. 24, 2004]

§411.389 Range of the advisory opinion.

(a) An advisory opinion states only CMS's opinion regarding the subject matter of the request. If the subject of an advisory opinion is an arrangement that must be approved by or is regulated by any other agency, CMS's advisory opinion cannot be read to indicate CMS's views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion that CMS issues under this part does not bind or obligate any agency other than the Department. It does not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

[69 FR 57230, Sept. 24, 2004]

Subpart K—Payment for Certain Excluded Services

§411.400 Payment for custodial care and services not reasonable and necessary.

(a) *Conditions for payment.* Notwithstanding the exclusions set forth in §411.15 (g) and (k). Medicare pays for ''custodial care'' and ''services not reasonable and necessary'' if the following conditions are met:

(1) The services were funished by a provider or by a practitioner or supplier that had accepted assignment of benefits for those services.

(2) Neither the beneficiary nor the provider, practitioner, or supplier knew, or could reasonably have been expected to know, that the services were excluded from coverage under §411.15 (g) or (k).

(b) *Time limits on payment.* (1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, payment may not be made for inpatient hospital care, posthospital SNF care, or home health services furnished after the earlier of the following:

(i) The day on which the beneficiary has been determined, under §411.404, to have knowledge, actual or imputed, that the services were excluded from coverage by reason of §411.15(g) or §411.15(k).

(ii) The day on which the provider has been determined, under §411.406 to have knowledge, actual or imputed, that the services are excluded from coverage by reason of §411.15(g) or §411.15(k).

(2) *Exception.* Payment may be made for services furnished during the first day after the limit established in paragraph (b)(1) of this section, if the QIO or the intermediary determines that the additional period of one day is necessary for planning post-discharge care. It the QIO or the intermediary determines that yet another day is necessary for planning post-discharge care, payment may be made for services furnished during the second day after the limit established in paragraph (b)(1) of this section.

§411.402 Indemnification of beneficiary.

(a) *Conditions for indemnification.* If Medicare payment is precluded because the conditions of §411.400(a)(2) are not met. Medicare indemnifies the beneficiary (and recovers from the provider, practitioner, or supplier), if the following conditions are met:

(1) The beneficiary paid the provider, practitioner, or supplier some or all of the charges for the excluded services.

(2) The beneficiary did not know and could not reasonably have been expected to know that the services were not covered.

(3) The provider, practitioner, or supplier knew, or could reasonably have been expected to know that the services were not covered.

(4) The beneficiary files a proper request for indemnification before the

end of the sixth month after whichever of the following is later:

(i) The month is which the beneficiary paid the provider, practitioner, or supplier.

(ii) The month in which the intermediary or carrier notified the beneficiary (or someone on his or her behalf) that the beneficiary would not be liable for the services.

For good cause shown by the beneficiary, the 6-month period may be extended.

(b) *Amount of indemnification.*[1] The amount of indemnification is the total that the beneficiary paid the provider, practitioner, or supplier.

(c) *Effect of indemnification.* The amount of indemnification is considered an overpayment to the provider, practitioner, or supplier, and as such is recoverable under this part or in accordance with other applicable provisions of law.

§ 411.404 Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A beneficiary who receives services that constitute custodial care under § 411.15(g) or that are not reasonable and necessary under § 411.15(k), is considered to have known that the services were not covered if the criteria of paragraphs (b) and (c) of this section are met.

(b) *Written notice.* (1) Written notice is given to the beneficiary, or to someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines.

(2) A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion.

(3) After a beneficiary is notified that there is no Medicare payment for a service that is not covered by Medicare, he or she is presumed to know that there is no Medicare payment for any form of subsequent treatment for the non-covered condition.

(c) *Source of notice.* The notice was given by one of the following:

(1) The QIO, intermediary, or carrier.

(2) The group or committee responsible for utilization review for the provider that furnished the services.

(3) The provider, practitioner, or supplier that furnished the service.

[54 FR 41734, Oct. 11, 1989, as amended at 69 FR 66423, Nov. 15, 2004]

§ 411.406 Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A provider, practitioner, or supplier that furnished services which constitute custodial care under § 411.15(g) or that are not reasonable and necessary under § 411.15(k) is considered to have known that the services were not covered if any one of the conditions specified in paragraphs (b) through (e) of this section is met.

(b) *Notice from the QIO, intermediary or carrier.* The QIO, intermediary, or carrier had informed the provider, practitioner, or supplier that the services furnished were not covered, or that similar or reasonably comparable services were not covered.

(c) *Notice from the utilization review committee or the beneficiary's attending phyician.* The utilization review group or committee for the provider or the beneficiary's attending physician had informed the provider that these services were not covered.

(d) *Notice from the provider, practitioner, or supplier to the beneficiary.* Before the services were furnished, the provider, practitioner or supplier informed the beneficiary that—

(1) The services were not covered; or

(2) The beneficiary no longer needed covered services.

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from

[1] For services furnished before 1988, the indemnification amount was reduced by any deductible or coinsurance amounts that would have been applied if the services had been covered.

intermediaries, carriers, or QIOs, including notification of QIO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a QIO.

(2) FEDERAL REGISTER publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 48425, Sept. 19, 1995]

§411.408 Refunds of amounts collected for physician services not reasonable and necessary, payment not accepted on an assignment-related basis.

(a) *Basic rule.* Except as provided in paragraph (d) of this section, a physician who furnishes a beneficiary services for which the physician does not undertake to claim payment on an assignment-related basis must refund any amounts collected from the beneficiary for services otherwise covered if Medicare payment is denied because the services are found to be not reasonable and necessary under §411.15(k).

(b) *Time limits for making refunds.* A timely refund of any incorrectly collected amounts of money must be made to the beneficiary to whom the services were furnished. A refund is timely if—

(1) A physician who does not request a review within 30 days after receipt of the denial notice makes the refund within that time period; or

(2) A physician who files a request for review within 30 days after receipt of the denial notice makes the refund within 15 days after receiving notice of an initial adverse review determination, whether or not the physician further appeals the initial adverse review determination.

(c) *Notices and appeals.* If payment is denied for nonassignment-related claims because the services are found to be not reasonable and necessary, a notice of denial will be sent to both the physician and the beneficiary. The physician who does not accept assignment will have the same rights as a physician who submits claims on an assignment-related basis, as detailed in subpart H of part 405 and subpart B of part 473, to appeal the determination, and will be subject to the same time limitations.

(d) *When a refund is not required.* A refund of any amounts collected for services not reasonable and necessary is not required if—

(1) The physician did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service; or

(2) Before the service was provided—

(i) The physician informed the beneficiary, or someone acting on the beneficiary's behalf, in writing that the physician believed Medicare was likely to deny payment for the specific service; and

(ii) The beneficiary (or someone eligible to sign for the beneficiary under §424.36(b) of this chapter) signed a statement agreeing to pay for that service.

(e) *Criteria for determining that a physician knew that services were excluded as not reasonable and necessary.* A physician will be determined to have known that furnished services were excluded from coverage as not reasonable and necessary if one or more of the conditions in §411.406 of this subpart are met.

(f) *Acceptable evidence of prior notice to a beneficiary that Medicare was likely to deny payment for a particular service.* To qualify for waiver of the refund requirement under paragraph (d)(2) of this section, the physician must inform the beneficiary (or person acting on his or her behalf) that the physician believes Medicare is likely to deny payment.

(1) The notice must—

(i) Be in writing, using approved notice language;

(ii) Cite the particular service or services for which payment is likely to be denied; and

(iii) Cite the physician's reasons for believing Medicare payment will be denied.

(2) The notice is not acceptable evidence if—

(i) The physician routinely gives this notice to all beneficiaries for whom he or she furnishes services; or

(ii) The notice is no more than a statement to the effect that there is a possibility that Medicare may not pay for the service.

(g) *Applicability of sanctions to physicians who fail to make refunds under this section.* A physician who knowingly and willfully fails to make refunds as required by this section may be subject to sanctions as provided for in chapter V, parts 1001, 1002, and 1003 of this title.

[55 FR 24568, June 18, 1990; 55 FR 35142, 35143, Aug. 28, 1990]

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), Sec. 124 of Pub. L. 106–113, 113 Stat. 1515, and Sec. 405 of Pub. L. of 108–173, 117 Stat. 2266, 42 U.S.C. 1305, 1395.

SOURCE: 50 FR 12741, Mar. 29, 1985, unless otherwise noted.

Subpart A—General Provisions

§412.1 Scope of part.

(a) *Purpose.* (1) This part implements sections 1886(d) and (g) of the Act by establishing a prospective payment system for the operating costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1983 and a prospective payment system for the capital-related costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1991. Under these prospective payment systems, payment for the operating and capital-related costs of inpatient hospital services furnished by hospitals subject to the systems (generally, short-term, acute-care hospitals) is made on the basis of prospectively determined rates and applied on a per discharge basis. Payment for other costs related to inpatient hospital services (organ acquisition costs incurred by hospitals with approved organ transplantation centers, the costs of qualified nonphysician anesthetist's services, as described in §412.113(c), and direct costs of approved nursing and allied health educational programs) is made on a reasonable cost basis. Payment for the direct costs of graduate medical education is made on a per resident amount basis in accordance with §§413.75—413.83 of this chapter. Additional payments are made for outlier cases, bad debts, indirect medical education costs, and for serving a disproportionate share of low-income patients. Under either prospective payment system, a hospital may keep the difference between its prospective payment rate and its operating or capital-related costs incurred in furnishing inpatient services, and the hospital is at risk for inpatient operating or inpatient capital-related costs that exceed its payment rate.

(2) This part implements section 124 of Public Law 106–113 by establishing a per diem prospective payment system for the inpatient operating and capital costs of hospital inpatient services furnished to Medicare beneficiaries by a psychiatric facility that meets the conditions of subpart N of this part.

(3) This part implements section 1886(j) of the Act by establishing a prospective payment system for the inpatient operating and capital costs of inpatient hospital services furnished to Medicare beneficiaries by a rehabilitation hospital or rehabilitation unit that meets the conditions of §412.604.

(4) This part implements section 123 of Public Law 106–113, which provides for the establishment of a prospective payment system for the costs of inpatient hospital services furnished to Medicare beneficiaries by long-term care hospitals described in section 1886(d)(1)(B)(iv) of the Act, for cost reporting periods beginning on or after October 1, 2002. This part also reflects the provisions of section 307 of Public Law 106–554, which state that the Secretary shall examine and may provide for appropriate adjustments to the long-term care hospital prospective payment system, including adjustments to diagnosis-related group (DRG) weights, area wage adjustments, geographic reclassification, outlier adjustments, updates, and disproportionate share adjustments consistent with section 1886(d)(5)(F) of the Act.

(b) *Summary of content.* (1) This subpart describes the basis of payment for inpatient hospital services under the prospective payment systems specified in paragraph (a)(1) of this section and sets forth the general basis of these systems.

(2) Subpart B sets forth the classifications of hospitals that are included in and excluded from the prospective payment systems specified in paragraph (a)(1) of this section, and sets forth requirements governing the inclusion or exclusion of hospitals in the systems as a result of changes in their classification.

(3) Subpart C sets forth certain conditions that must be met for a hospital to receive payment under the prospective payment systems specified in paragraph (a)(1) of this section.

(4) Subpart D sets forth the basic methodology by which prospective payment rates for inpatient operating costs are determined under the prospective payment system specified in paragraph (a)(1) of this section.

(5) Subpart E describes the transition ratesetting methods that are used to determine transition payment rates for inpatient operating costs during the first 4 years of the prospective payment system specified in paragraph (a)(1) of this section.

(6) Subpart F sets forth the methodology for determining payments for outlier cases under the prospective payment system specified in paragraph (a)(1) of this section.

(7) Subpart G sets forth rules for special treatment of certain facilities under the prospective payment system specified in paragraph (a)(1) of this section for inpatient operating costs.

(8) Subpart H describes the types, amounts, and methods of payment to hospitals under the prospective payment system specified in paragraph (a)(1) of this section for inpatient operating costs.

(9) Subpart K describes how the prospective payment system specified in paragraph (a)(1) of this section for inpatient operating costs is implemented for hospitals located in Puerto Rico.

(10) Subpart L sets forth the procedures and criteria concerning applications from hospitals to the Medicare Geographic Classification Review Board for geographic redesignation under the prospective payment systems specified in paragraph (a)(1) of this section.

(11) Subpart M describes how the prospective payment system specified in paragraph (a)(1) of this section for inpatient capital-related costs is implemented effective with reporting periods beginning on or after October 1, 1991.

(12) Subpart N describes the prospective payment system specified in paragraph (a)(2) of this section for inpatient psychiatric facilities and sets forth the general methodology for paying the operating and capital-related costs of inpatient hospital services furnished by inpatient psychiatric facilities effective with cost reporting periods beginning on or after January 1, 2005.

(13) Subpart O of this part describes the prospective payment system specified in paragraph (a)(4) of this section for long-term care hospitals and sets forth the general methodology for paying for the operating and capital-related costs of inpatient hospital services furnished by long-term care hospitals, effective with cost reporting periods beginning on or after October 1, 2002.

(14) Subpart P describes the prospective payment system specified in paragraph (a)(3) of this section for rehabilitation hospitals and rehabilitation units and sets forth the general methodology for paying for the operating and capital-related costs of inpatient hospital services furnished by rehabilitation hospitals and rehabilitation units effective with cost reporting periods beginning on or after January 1, 2002.

[66 FR 41385, Aug. 7, 2001, as amended at 67 FR 56048, Aug. 30, 2002; 69 FR 66976, Nov. 15, 2004; 70 FR 47484, Aug. 12, 2005]

§ 412.2 Basis of payment.

(a) *Payment on a per discharge basis.* Under both the inpatient operating and inpatient capital-related prospective payment systems, hospitals are paid a predetermined amount per discharge for inpatient hospital services furnished to Medicare beneficiaries. The prospective payment rate for each discharge (as defined in § 412.4) is determined according to the methodology described in subpart D, E, or G of this part, as appropriate, for operating costs, and according to the methodology described in subpart M of this part for capital-related costs. An additional payment is made for both inpatient operating and inpatient capital-related costs, in accordance with subpart F of this part, for cases that are extraordinarily costly to treat.

(b) *Payment in full.* (1) The prospective payment amount paid for inpatient hospital services is the total Medicare payment for the inpatient operating costs (as described in paragraph (c) of this section) and the inpatient capital-related costs (as described in paragraph (d) of this section) incurred in furnishing services covered by the Medicare program.

(2) The full prospective payment amount, as determined under subpart D, E, or G and under subpart M of this part, is made for each stay during which there is at least one Medicare payable day of care. Payable days of care, for purposes of this paragraph include the following:

(i) Limitation of liability days payable under the payment procedures for custodial care and services that are not reasonable and necessary as specified in §411.400 of this chapter.

(ii) Guarantee of payment days, as authorized under §409.68 of this chapter, for inpatient hospital services furnished to an individual whom the hospital has reason to believe is entitled to Medicare benefits at the time of admission.

(3) If a patient is admitted to an acute care hospital and then the acute care hospital meets the criteria at §412.23(e) to be paid as a LTCH, during the course of the patient's hospitalization, Medicare considers all the days of the patient stay in the facility (days prior to and after the designation of LTCH status) to be a single episode of LTCH care. Medicare will not make payment under subpart H for any part of the hospitalization. Payment for the entire patient stay (days prior to and after the designation of LTCH status) will be made in accordance with the requirements specified in §412.521. The requirements of this paragraph (b)(3) apply only to a patient stay in which a patient is in an acute care hospital and that hospital is designated as a LTCH on or after October 1, 2004.

(c) *Inpatient operating costs.* The prospective payment system provides a payment amount for inpatient operating costs, including—

(1) Operating costs for routine services (as described in §413.53(b) of this chapter), such as the costs of room, board, and routine nursing services;

(2) Operating costs for ancillary services, such as radiology and laboratory services furnished to hospital inpatients;

(3) Special care unit operating costs (intensive care type unit services, as described in §413.53(b) of this chapter);

(4) Malpractice insurance costs related to services furnished to inpatients; and

(5) Preadmission services otherwise payable under Medicare Part B furnished to a beneficiary during the 3 calendar days immediately preceding the date of the beneficiary's admission to the hospital that meet the following conditions:

(i) The services are furnished by the hospital or by an entity wholly owned or operated by the hospital. An entity is wholly owned by the hospital if the hospital is the sole owner of the entity. An entity is wholly operated by a hospital if the hospital has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity.

(ii) For services furnished after January 1, 1991, the services are diagnostic (including clinical diagnostic laboratory tests).

(iii) For services furnished on or after October 1, 1991, the services are furnished in connection with the principal diagnosis that requires the beneficiary to be admitted as an inpatient and are not the following:

(A) Ambulance services.

(B) Maintenance renal dialysis.

(d) *Inpatient capital-related costs.* For cost reporting periods beginning on or after October 1, 1991, the capital prospective payment system provides a payment amount for inpatient hospital capital-related costs as described in part 413, subpart G of this chapter.

(e) *Excluded costs.* The following inpatient hospital costs are excluded from the prospective payment amounts and are paid for on a reasonable cost basis:

(1) Capital-related costs for cost reporting periods beginning before October 1, 1991, and an allowance for return on equity, as described in §§413.130 and 413.157, respectively, of this chapter.

(2) Direct medical education costs for approved nursing and allied health education programs as described in §413.85 of this chapter.

(3) Costs for direct medical and surgical services of physicians in teaching hospitals exercising the election in §405.521 of this chapter.

(4) The acquisition costs of hearts, kidneys, livers, lungs, pancreas, and intestines (or multivisceral organs) incurred by approved transplantation centers.

(5) The costs of qualified nonphysician anesthetists' services, as described in §412.113(c).

(f) *Additional payments to hospitals.* In addition to payments based on the prospective payment system rates for inpatient operating and inpatient capital-related costs, hospitals receive payments for the following:

(1) Outlier cases, as described in subpart F of this part.

(2) The indirect costs of graduate medical education, as specified in subparts F and G of this part and in § 412.105 for inpatient operating costs and in § 412.322 for inpatient capital-related costs.

(3) Costs excluded from the prospective payment rates under paragraph (e) of this section, as provided in § 412.115.

(4) Bad debts of Medicare beneficiaries, as provided in § 412.115(a).

(5) ESRD beneficiary discharges if such discharges are ten percent or more of the hospital's total Medicare discharges, as provided in § 412.104.

(6) Serving a disproportionate share of low-income patients, as provided in § 412.106 for inpatient operating costs and § 412.320 for inpatient capital-related costs.

(7) The direct graduate medical education costs for approved residency programs in medicine, osteopathy, dentistry, and podiatry as described in §§ 413.75—413.83 of this chapter.

(8) For discharges on or after June 19, 1990, and before October 1, 1994, and for discharges on or after October 1, 1997, a payment amount per unit for blood clotting factor provided to Medicare inpatients who have hemophilia. For discharges occurring on or after October 1, 2005, the additional payment is made based on the average sales price methodology specified in Subpart K, Part 414 of this subchapter and the furnishing fee specified in § 410.63 of this subchapter.

(9) Special additional payment for certain new technology as specified in §§ 412.87 and 412.88 of Subpart F.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 52 FR 33057, Sept. 1, 1987; 53 FR 38526, Sept. 30, 1988; 55 FR 15173, Apr. 20, 1990; 55 FR 36068, Sept. 4, 1990; 57 FR 33897, July 31, 1992; 57 FR 39819, Sept. 1, 1992; 57 FR 46510, Oct. 9, 1992; 58 FR 46337, Sept. 1, 1993; 59 FR 1658, Jan. 12, 1994; 59 FR 45396, Sept. 1, 1994; 62 FR 46025, Aug. 29, 1997; 63 FR 6868, Feb. 11, 1998; 64 FR 41540, July 30, 1999; 65 FR 47106, Aug. 1, 2000; 66 FR 39933, Aug. 1, 2001; 66 FR 46924, Sept. 7, 2001; 69 FR 49240, Aug. 11, 2004; 70 FR 47484, Aug. 12, 2005]

§ 412.4 Discharges and transfers.

(a) *Discharges.* Subject to the provisions of paragraphs (b) and (c) of this section, a hospital inpatient is considered discharged from a hospital paid under the prospective payment system when—

(1) The patient is formally released from the hospital; or

(2) The patient dies in the hospital.

(b) *Acute care transfers.* A discharge of a hospital inpatient is considered to be a transfer for purposes of payment under this part if the patient is readmitted the same day (unless the readmission is unrelated to the initial discharge) to another hospital that is—

(1) Paid under the prospective payment system described in subparts A through M of this part; or

(2) Excluded from being paid under the prospective payment system described in subparts A through M of this part because of participation in an approved statewide cost control program as described in subpart C of part 403 of this chapter.

(c) *Postacute care transfers.* A discharge of a hospital inpatient is considered to be a transfer for purposes of this part when the patient's discharge is assigned, as described in § 412.60(c), to one of the qualifying diagnosis-related groups (DRGs) listed in paragraph (d) of this section and the discharge is made under any of the following circumstances:

(1) To a hospital or distinct part hospital unit excluded from the prospective payment system described in subparts A through M of this part under subpart B of this part.

(2) To a skilled nursing facility.

(3) To home under a written plan of care for the provision of home health services from a home health agency and those services begin within 3 days after the date of discharge.

(d) *Qualifying DRGs.* (1) For a fiscal year prior to FY 2006, for purposes of paragraph (c) of this section, and subject to the provisions of paragraph (d)(2) of this section, the qualifying DRGs must meet the following criteria for both of the 2 most recent years for which data are available:

(i) The DRG must have a geometric mean length of stay of at least 3 days.

(ii) The DRG must have at least 14,000 cases identified as postacute care transfer cases.

(iii) The DRG must have at least 10 percent of the postacute care transfers occurring before the geometric mean length of stay for the DRG.

(iv) If the DRG is one of a paired DRG based on the presence or absence of a comorbidity or complication, one of the DRGs meets the criteria specified under paragraphs (d)(1)(i) through (d)(1)(iii) of this section.

(v) To initially qualify, the DRG must meet the criteria specified in paragraphs (d)(1)(i) through (d)(1)(iv) of this section and must have a decline in the geometric mean length of stay for the DRG during the most recent 5 years of at least 7 percent. Once a DRG initially qualifies, the DRG is subject to the criteria specified in paragraphs (d)(1)(i) through (d)(1)(iv) of this section for each subsequent fiscal year.

(2) For purposes of paragraph (c), a discharge is also considered to be a transfer if it meets the following conditions:

(i) The discharge is assigned to a DRG that contains only cases that were assigned to a DRG that qualified under this paragraph within the previous 2 years; and

(ii) The latter DRG was split or otherwise modified within the previous 2 fiscal years.

(3) For fiscal years beginning with FY 2006, for purposes of paragraph (c) of this section—

(i) The qualifying DRGs must meet the following criteria using data from the March 2005 update of the FY 2004 MedPAR file and Version 23.0 of the DRG Definitions Manual (FY 2006):

(A) The DRG has at least 2,050 total postacute care transfer cases;

(B) At least 5.5 percent of the cases in the DRG are discharged to postacute care prior to the geometric mean length of stay for the DRG;

(C) The DRG must have a geometric mean length of stay greater than 3 days;

(D) The DRG is paired with a DRG based on the presence or absence of a comorbidity or complication or major cardiovascular condition that, it meets the criteria specified in paragraphs (d)(3)(i)(A) and (d)(3)(ii)(B) of this section.

(ii) If a DRG did not exist in Version 23.0 of the DRG Definitions Manual or a DRG included in Version 23.0 of the DRG Definitions Manual is revised, the DRG will be a qualifying DRG if it meets the following criteria based on the version of the DRG Definitions Manual in use when the new or revised DRG first becomes effective, using the most recent complete year of MedPAR data:

(A) The total number of discharges to postacute care in the DRG must equal or exceed the 55th percentile for all DRGs;

(B) The proportion of short-stay discharges to postacute care to total discharges in the DRG exceeds the 55th percentile for all DRGs; and

(C) The DRG is paired with a DRG based on the presence or absence of a comorbidity or a complication or major cardiovascular condition that meets the criteria specified under paragraph (d)(3)(ii)(A) and (d)(3)(ii)(B) of this section.

(e) *Payment for discharges.* The hospital discharging an inpatient (under paragraph (a) of this section) is paid in full, in accordance with §412.2(b).

(f) *Payment for transfers.* (1) *General rule.* Except as provided in paragraph (f)(2) or (f)(3) of this section, a hospital that transfers an inpatient under the circumstances described in paragraph (b) or (c) of this section, is paid a graduated per diem rate for each day of the patient's stay in that hospital, not to exceed the amount that would have been paid under subparts D and M of this part if the patient had been discharged to another setting. The per diem rate is determined by dividing the

appropriate prospective payment rate (as determined under subparts D and M of this part) by the geometric mean length of stay for the specific DRG to which the case is assigned. Payment is graduated by paying twice the per diem amount for the first day of the stay, and the per diem amount for each subsequent day, up to the full DRG payment.

(2) *Special rule for DRGs 209, 210, and 211 for fiscal years prior to FY 2006.* For fiscal years prior to FY 2006, a hospital that transfers an inpatient under the circumstances described in paragraph (c) of this section and the transfer is assigned to DRGs 209, 210, or 211 is paid as follows:

(i) 50 percent of the appropriate prospective payment rate (as determined under subparts D and M of this part) for the first day of the stay; and

(ii) 50 percent of the amount calculated under paragraph (f)(1) of this section for each day of the stay, up to the full DRG payment.

(3) *Transfer assigned to DRG 385.* If a transfer is classified into DRG 385 (Neonates, died or transferred) the transferring hospital is paid in accordance with § 412.2(b).

(4) *Outliers.* Effective with discharges occurring on or after October 1, 1984, a transferring hospital may qualify for an additional payment for extraordinarily high-cost cases that meet the criteria for cost outliers as described in subpart F of this part.

(5) *Special rule for DRGs meeting specific criteria.* For discharges occurring on or after October 1, 2005, a hospital that transfers an inpatient under the circumstances described in paragraph (c) of this section is paid using the provisions of paragraph (f)(2)(i) and (f)(2)(ii) of this section if the transfer case is assigned to one of the DRGs meeting the following criteria:

(i) The DRG meets the criteria specified in paragraph (d)(3)(i) or (d)(3)(iii) of this section;

(ii) The average charges of the 1-day discharge cases in the DRG must be at least 50 percent of the average charges for all cases in the DRG; and

(iii) The geometric mean length of stay for the DRG is greater than 4 days; and

(iv) If a DRG is a paired with a DRG based on the presence or absence of a comorbidity or complication or a major cardiovascular complication that meets the criteria specified in paragraph (f)(5)(i) through (f)(5)(iii) of this section, that DRG will also be paid under the provisions of paragraph (f)(2)(i) and (f)(2)(ii) of this section.

[63 FR 41003, July 31, 1998, as amended at 65 FR 47106, Aug. 1, 2000; 67 FR 50111, Aug. 1, 2002; 68 FR 45469, Aug. 1, 2003; 69 FR 49240, Aug. 11, 2004; 70 FR 47484, Aug. 12, 2005]

§ 412.6 Cost reporting periods subject to the prospective payment systems.

(a) *Initial cost reporting period for each prospective payment system.* (1) Each subject hospital is paid under the prospective payment system for operating costs for inpatient hospital services effective with the hospital's first cost reporting period beginning on or after October 1, 1983 and for inpatient capital-related costs effective with the hospital's first cost reporting period beginning on or after October 1, 1991.

(2) The hospital is paid the applicable prospective payment rate for inpatient operating costs and capital-related costs for each discharge occurring on or after the first day of its first cost reporting period subject to the applicable prospective payment system.

(3) If a discharged beneficiary was admitted to the hospital before the first day of the hospital's first cost reporting period subject to the prospective payment system for inpatient operating costs, the reasonable costs of services furnished before that day are paid under the cost reimbursement provisions of part 413 of this chapter. For such discharges, the amount otherwise payable under the applicable prospective payment rate is reduced by the amount paid on a reasonable cost basis for inpatient hospital services furnished to that beneficiary during the hospital stay. If the amount paid under reasonable cost exceeds the inpatient operating prospective payment amount, the reduction is limited to the inpatient operating prospective payment amount.

(b) *Changes in cost reporting periods.* CMS recognizes a change in a hospital's cost reporting period made after November 30, 1982 only if the change

has been requested in writing by the hospital and approved by the intermediary in accordance with § 413.24(f)(3) of this chapter.

[57 FR 39819, Sept. 1, 1992]

§ 412.8 Publication of schedules for determining prospective payment rates.

(a) *Initial prospective payment rates*—(1) *For inpatient operating costs.* Initial prospective payment rates for inpatient operating costs (for the period October 1, 1983 through September 30, 1984) were determined in accordance with documents published in the FEDERAL REGISTER on September 1, 1983 (48 FR 39838), and January 3, 1984 (49 FR 324).

(2) *For inpatient capital-related costs.* Initial prospective payment rates for inpatient capital-related costs (for the period October 1, 1991 through September 30, 1992) were determined in accordance with the final rule published in the FEDERAL REGISTER on August 30, 1991 (56 FR 43196).

(b) *Annual publication of schedule for determining prospective payment rates.* (1) CMS proposes changes in the methods, amounts, and factors used to determine inpatient prospective payment rates in a FEDERAL REGISTER document published for public comment not later than the April 1 before the beginning of the Federal fiscal year in which the proposed changes would apply.

(2) CMS publishes a FEDERAL REGISTER document setting forth final methods, amounts, and factors for determining inpatient prospective payment rates not later than the August 1 before the Federal fiscal year in which the rates would apply.

[57 FR 39820, Sept. 1, 1992, as amended at 62 FR 46025, Aug. 29, 1997]

§ 412.10 Changes in the DRG classification system.

(a) *General rule.* CMS issues changes in the DRG classification system in a FEDERAL REGISTER notice at least annually. Except as specified in paragraphs (c) and (d) of this section, the DRG changes are effective prospectively with discharges occurring on or after the same date the payment rates are effective.

(b) *Basis for changes in the DRG classification system.* All changes in the DRG classification system are made using the principles established for the DRG system. This means that cases are classified so each DRG is—

(1) Clinically coherent; and

(2) Embraces an acceptable range of resource consumption.

(c) *Interim coverage changes*—(1) *Criteria.* CMS makes interim changes to the DRG classification system during the Federal fiscal year to incorporate items and services newly covered under Medicare.

(2) *Implementation and effective date.* CMS issues interim coverage changes through its administrative issuance system and makes the change effective as soon as is administratively feasible.

(3) *Publication for comment.* CMS publishes any change made under paragraph (c)(1) of this section in the next annual notice of changes to the DRG classification system published in accordance with paragraph (a) of this section.

(d) *Interim changes to correct omissions and inequities*—(1) *Criteria.* CMS makes interim changes to the DRG classification system to correct a serious omission or inequity in the system only if failure to make the changes would have—

(i) A potentially substantial adverse impact on the health and safety of beneficiaries; or

(ii) A significant and unwarranted fiscal impact on hospitals or the Medicare program.

(2) *Publication and effective date.* CMS publishes these changes in the FEDERAL REGISTER in a final notice with comment period with a prospective effective date. The change is also published for public information in the next annual notice of changes to the DRG classification system published in accordance with paragraph (a) of this section.

(e) *Review by ProPAC.* Changes published annually in accordance with paragraph (a) of this section are subject to review and comment by ProPAC upon publication. Interim changes to the DRG classification system that are made in accordance with paragraphs (c)

and (d) of this section are subject to review by ProPAC before implementation.

[50 FR 35688, Sept. 3, 1985, as amended at 51 FR 31496, Sept. 3, 1986; 57 FR 39820, Sept. 1, 1992]

Subpart B—Hospital Services Subject to and Excluded From the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

§ 412.20 Hospital services subject to the prospective payment systems.

(a) Except for services described in paragraphs (b), (c), (d), and (e) of this section, all covered hospital inpatient services furnished to beneficiaries during the subject cost reporting periods are paid under the prospective payment system as specified in § 412.1(a)(1).

(b) Effective for cost reporting periods beginning on or after January 1, 2005, covered inpatient hospital services furnished to Medicare beneficiaries by a inpatient psychiatric facility that meets the conditions of § 412.404 are paid under the prospective payment system described in subpart N of this part.

(c)(1) Effective for cost reporting periods beginning on or after January 1, 2002, covered inpatient hospital services furnished to Medicare beneficiaries by a rehabilitation hospital or rehabilitation unit that meet the conditions of § 412.604 are paid under the prospective payment system described in subpart P of this part.

(2) CMS will not pay for services under Subpart P of this part if the services are paid for by a health maintenance organization (HMO) or competitive medical plan (CMP) that elects not to have CMS make payments to an inpatient rehabilitation facility for services, which are inpatient hospital services, furnished to the HMO's or CMP's Medicare enrollees, as provided under part 417 of this chapter.

(d) Effective for cost reporting periods beginning on or after October 1, 2002, covered inpatient hospital services furnished to Medicare beneficiaries by a long-term care hospital that meets the conditions for payment of §§ 412.505 through 412.511 are paid under the prospective payment system described in subpart O of this part.

(e) Inpatient hospital services will not be paid under the prospective payment systems specified in § 412.1(a)(1) under any of the following circumstances:

(1) The services are furnished by a hospital (or hospital unit) explicitly excluded from the prospective payment systems under §§ 412.23, 412.25, 412.27, and 412.29.

(2) The services are emergency services furnished by a nonparticipating hospital in accordance with § 424.103 of this chapter.

(3) The services are paid for by an HMO or competitive medical plan (CMP) that elects not to have CMS make payments directly to a hospital for inpatient hospital services furnished to the HMO's or CMP's Medicare enrollees, as provided in § 417.240(d) and § 417.586 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 39820, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994; 66 FR 41386, Aug. 7, 2001; 67 FR 56048, Aug. 30, 2002; 68 FR 45698, Aug. 1, 2003; 69 FR 66976, Nov. 15, 2004]

§ 412.22 Excluded hospitals and hospital units: General rules.

(a) *Criteria.* Subject to the criteria set forth in paragraph (e) of this section, a hospital is excluded from the prospective payment systems specified in § 412.1(a)(1) of this part if it meets the criteria for one or more of the excluded classifications described in § 412.23. For purposes of this subpart, the term ''hospital'' includes a critical access hospital (CAH).

(b) *Cost reimbursement.* Except for those hospitals specified in paragraph (c) of this section, and § 412.20(b), (c), and (d), all excluded hospitals (and excluded hospital units, as described in § 412.23 through § 412.29) are reimbursed under the cost reimbursement rules set forth in part 413 of this chapter, and are subject to the ceiling on the rate of hospital cost increases as specified in § 413.40 of this chapter.

(c) *Special payment provisions.* The following classifications of hospitals are paid under special provisions and therefore are not generally subject to

the cost reimbursement or prospective payment rules of this chapter.

(1) Veterans Administration hospitals.

(2) Hospitals reimbursed under State cost control systems approved under part 403 of this chapter.

(3) Hospitals reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 (42 U.S.C. 1395b–1) or section 222(a) of Public Law 92–603 (42 U.S.C. 1395b–1 (note)).

(4) Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

(d) *Changes in hospitals' status.* For purposes of exclusion from the prospective payment systems under this subpart, the status of each currently participating hospital (excluded or not excluded) is determined at the beginning of each cost reporting period and is effective for the entire cost reporting period. Any changes in the status of the hospital are made only at the start of a cost reporting period.

(e) *Hospitals-within-hospitals.* Except as provided in paragraph (f) of this section, a hospital that occupies space in a building also used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital, must meet the following criteria in order to be excluded from the prospective payment systems specified in § 412.1(a)(1):

(1) Except as specified in paragraph (f) of this section, for cost reporting periods beginning on or after October 1, 1997—

(i) *Separate governing body.* The hospital has a governing body that is separate from the governing body of the hospital occupying space in the same building or on the same campus. The hospital's governing body is not under the control of the hospital occupying space in the same building or on the same campus, or of any third entity that controls both hospitals.

(ii) *Separate chief medical officer.* The hospital has a single chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of the hospital. The chief medical officer of the hospital is not employed by or under contract with either the hospital occupying space in the same building or on the same campus or any third entity that controls both hospitals.

(iii) *Separate medical staff.* The hospital has a medical staff that is separate from the medical staff of the hospital occupying space in the same building or on the same campus. The hospital's medical staff is directly accountable to the governing body for the quality of medical care provided in the hospital, and adopts and enforces by-laws governing medical staff activities, including criteria and procedures for recommending to the governing body the privileges to be granted to individual practitioners.

(iv) *Chief executive officer.* The hospital has a single chief executive officer through whom all administration authority flows, and who exercises control and surveillance over all administrative activities of the hospital. The chief executive officer is not employed by, or under contract with, either the hospital occupying space in the same building or on the same campus or any third entity that controls both hospitals.

(v) *Performance of basic hospital functions.* The hospital meets one of the following criteria:

(A) The hospital performs the basic functions specified in §§ 482.21 through 482.27, 482.30, 482.42, 482.43, and 482.45 of this chapter through the use of employees or under contracts or other agreements with entities other than the hospital occupying space in the same building or on the same campus, or a third entity that controls both hospitals. Food and dietetic services and housekeeping, maintenance, and other services necessary to maintain a clean and safe physical environment could be obtained under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals.

(B) For the same period of at least 6 months used to determine compliance with the criterion regarding the age of patients in § 412.23(d)(2) or the length-of-stay criterion in § 412.23(e)(2), or for hospitals other than children's or long-term care hospitals, for a period of at least 6 months immediately preceding

the first cost reporting period for which exclusion is sought, the cost of the services that the hospital obtains under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals, is no more than 15 percent of the hospital's total inpatient operating costs, as defined in § 412.2(c). For purposes of this paragraph (e)(1)(v)(B), however, the costs of preadmission services are those specified under § 413.40(c)(2) rather than those specified under § 412.2(c)(5).

(C) For the same period of at least 6 months used to determine compliance with the criterion regarding the age of inpatients in § 412.23(d)(2) or the length-of-stay criterion in § 412.23(e)(2), or for hospitals other than children's or long-term care hospitals, for the period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the hospital has an inpatient population of whom at least 75 percent were referred to the hospital from a source other than another hospital occupying space in the same building or on the same campus.

(2) Effective for long-term care hospitals-within-hospitals for cost reporting periods beginning on or after October 1, 2004, the hospital must meet the governance and control requirements at paragraphs (e)(1)(i) through (e)(1)(iv) of this section.

(3) *Notification of co-located status.* A long-term care hospital that occupies space in a building used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital and that meets the criteria of paragraphs (e)(1) or (e)(2) of this section must notify its fiscal intermediary and CMS in writing of its co-location and identify by name, address, and Medicare provider number those hospital(s) with which it is co-located.

(f) *Application for certain hospitals.* If a hospital was excluded from the prospective payment systems under the provisions of this section on or before September 30, 1995, and at that time occupied space in a building also used by another hospital, or in one or more buildings located on the same campus as buildings used by another hospital, the criteria in paragraph (e) of this section do not apply to the hospital as long as the hospital either—

(1) Continues to operate under the same terms and conditions, including the number of beds and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 1995; or

(2) In the case of a hospital that changes the terms and conditions under which it operates after September 30, 1995, but before October 1, 2003, continues to operate under the same terms and conditions, including the number of beds and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 2003.

(g) *Definition of control.* For purposes of this section, control exists if an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

(h) *Satellite facilities.* (1) For purposes of paragraphs (h)(2) through (h)(4) of this section, a satellite facility is a part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

(2) Except as provided in paragraphs (h)(3), (h)(6), and (h)(7) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

(i) In the case of a hospital (other than a children's hospital) that was excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the hospital's number of State-licensed and Medicare-certified beds, including those at the satellite facilities, does not exceed the hospital's number of State-licensed and Medicare-certified beds on the last day of the hospital's last cost reporting period beginning before October 1, 1997.

(ii) The satellite facility independently complies with—

(A) For psychiatric hospitals, the requirements under § 412.23(a);

(B) For rehabilitation hospitals, the requirements under § 412.23(b)(2);

(C) For the children's hospitals, the requirements under § 412.23(d)(2); or

(D) For long-term care hospitals, the requirements under §§ 412.23(e)(1) through (e)(3)(i).

(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.

(D) It is serviced by the same fiscal intermediary as the hospital of which it is a part.

(E) It is treated as a separate cost center of the hospital of which it is a part.

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.

(3) Except as provided in paragraph (h)(4) of this section, the provisions of paragraph (h)(2) of this section do not apply to—

(i) Any hospital structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the hospital continues operating under the same terms and conditions, including the number of beds and square footage considered, for purposes of Medicare participation and payment, to be part of the hospital, in effect on September 30, 1999; or

(ii) Any hospital excluded from the prospective payment systems under § 412.23(e)(2)(ii).

(4) In applying the provisions of paragraph (h)(3) of this section, any hospital structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility if these changes are made necessary by relocation of a facility—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(5) *Notification of co-located status.* A satellite of a long-term care hospital that occupies space in a building used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital and that meets the criteria of paragraphs (h)(1) through (h)(4) of this section must notify its fiscal intermediary and CMS in writing of its co-location and identify by name, address, and Medicare provider number, those hospital(s) with which it is co-located.

(6) The provisions of paragraph (h)(2)(i) of this section do not apply to any long-term care hospital that is subject to the long-term care hospital prospective payment system under Subpart O of this subpart, effective for cost reporting periods occurring on or after October 1, 2002, and that elects to be paid based on 100 percent of the Federal prospective payment rate as specified in § 412.533(c), beginning with the first cost reporting period following that election, or when the LTCH is fully transitioned to 100 percent of the Federal prospective rate, or to a new long-term care hospital, as defined in § 412.23(e)(4).

(7) The provisions of paragraph (h)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment

system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 57 FR 39820, Sept. 1, 1994; 62 FR 46026, Aug. 29, 1997; 63 FR 26357, May 12, 1998; 64 FR 41540, July 30, 1999; 66 FR 41386, Aug. 7, 2001; 67 FR 50111, Aug. 1, 2002; 67 FR 56048, Aug. 30, 2002; 68 FR 10988, Mar. 7, 2003; 68 FR 34162, June 6, 2003; 68 FR 45469, Aug. 1, 2003; 69 FR 49240, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 69 FR 66976, Nov. 15, 2004; 70 FR 24222, May 6, 2005]

§ 412.23 Excluded hospitals: Classifications.

Hospitals that meet the requirements for the classifications set forth in this section are not reimbursed under the prospective payment systems specified in § 412.1(a)(1):

(a) *Psychiatric hospitals.* A psychiatric hospital must—

(1) Meet the following requirements to be excluded from the prospective payment system as specified in § 412.1(a)(1) and to be paid under the prospective payment system as specified in § 412.1(a)(2) and in subpart N of this part;

(2) Be primarily engaged in providing, by or under the supervision of a psychiatrist, psychiatric services for the diagnosis and treatment of mentally ill persons; and

(3) Meet the conditions of participation for hospitals and special conditions of participation for psychiatric hospitals set forth in part 482 of this chapter.

(b) *Rehabilitation hospitals.* A rehabilitation hospital must meet the following requirements to be excluded from the prospective payment systems specified in § 412.1(a)(1) and to be paid under the prospective payment system specified in § 412.1(a)(3) and in Subpart P of this part:

(1) Have a provider agreement under part 489 of this chapter to participate as a hospital.

(2) Except in the case of a newly participating hospital seeking classification under this paragraph as a rehabilitation hospital for its first 12-month cost reporting period, as described in paragraph (b)(8) of this section, a hospital must show that during its most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), it served an inpatient population that meets the criteria under paragraph (b)(2)(i) or (b)(2)(ii) of this section.

(i) For cost reporting periods beginning on or after July 1, 2004 and before July 1, 2005, the hospital has served an inpatient population of whom at least 50 percent, and for cost reporting periods beginning on or after July 1, 2005 and before July 1, 2006, the hospital has served an inpatient population of whom at least 60 percent, and for cost reporting periods beginning on or after July 1, 2006 and before July 1, 2007, the hospital has served an inpatient population of whom at least 65 percent, required intensive rehabilitative services for treatment of one or more of the conditions specified at paragraph (b)(2)(iii) of this section. A patient with a comorbidity, as defined at § 412.602, may be included in the inpatient population that counts towards the required applicable percentage if—

(A) The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in paragraph (b)(2)(iii) of this section;

(B) The patient has a comorbidity that falls in one of the conditions specified in paragraph (b)(2)(iii) of this section; and

(C) The comorbidity has caused significant decline in functional ability in the individual such that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under subpart P of this part and that cannot be appropriately performed in another care setting covered under this title.

(ii) For cost reporting periods beginning on or after July 1, 2007, the hospital has served an inpatient population of whom at least 75 percent required intensive rehabilitative services for treatment of one or more of the conditions specified in paragraph (b)(2)(iii) of this section. A patient with comorbidity as described in paragraph (b)(2)(i) is not included in the inpatient population that counts towards the required 75 percent.

(iii) *List of conditions.*

(A) Stroke.

(B) Spinal cord injury.

(C) Congenital deformity.

(D) Amputation.

(E) Major multiple trauma.

(F) Fracture of femur (hip fracture).

(G) Brain injury.

(H) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.

(I) Burns.

(J) Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(K) Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(L) Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

(M) Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:

(*1*) The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.

(*2*) The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.

(*3*) The patient is age 85 or older at the time of admission to the IRF.

(3) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program or assessment.

(4) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social or psychological services, and orthotic and prosthetic services.

(5) Have a director of rehabilitation who—

(i) Provides services to the hospital and its inpatients on a full-time basis;

(ii) Is a doctor of medicine or osteopathy;

(iii) Is licensed under State law to practice medicine or surgery; and

(iv) Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical-management of inpatients requiring rehabilitation services.

(6) Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

(7) Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment, and that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(8) A hospital that seeks classification under this paragraph as a rehabilitation hospital for the first full 12-month cost reporting period that occurs after it becomes a Medicare-participating hospital may provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b)(2) of this section, instead of showing that it has treated that population during its most recent 12-month cost reporting period. The written certification is also effective for any cost reporting period of not less than one month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period.

(9) For cost reporting periods beginning on or after October 1, 1991, if a hospital is excluded from the prospective payment systems specified in § 412.1(a)(1) or is paid under the prospective payment system specified in § 412.1(a)(3) for a cost reporting period under paragraph (b)(8) of this section, but the inpatient population it actually treated during that period does not meet the requirements of paragraph (b)(2) of this section, we adjust payments to the hospital retroactively in accordance with the provisions in § 412.130.

(c) [Reserved]

(d) *Children's hospitals.* A children's hospital must—

(1) Have a provider agreement under part 489 of this chapter to participate as a hospital; and

(2) Be engaged in furnishing services to inpatients who are predominantly individuals under the age of 18.

(e) *Long-term care hospitals.* A long-term care hospital must meet the requirements of paragraph (e)(1) and (e)(2) of this section and, when applicable, the additional requirement of § 412.22(e), to be excluded from the prospective payment system specified in § 412.1(a)(1) and to be paid under the prospective payment system specified in § 412.1(a)(4) and in Subpart O of this part.

(1) *Provider agreements.* The hospital must have a provider agreement under Part 489 of this chapter to participate as a hospital; and

(2) *Average length of stay.* (i) The hospital must have an average Medicare inpatient length of stay of greater than 25 days (which includes all covered and noncovered days of stay of Medicare patients) as calculated under paragraph (e)(3) of this section; or

(ii) For cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the prospective payment system under this section in 1986 meets the length of stay criterion if it has an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days and demonstrates that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in fiscal year 1997 have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(3) *Calculation of average length of stay.* (i) Subject to the provisions of paragraphs (e)(3)(ii) through (e)(3)(iv) of this section, the average Medicare inpatient length of stay specified under paragraph (e)(2)(i) of this section is calculated by dividing the total number of covered and noncovered days of stay of Medicare inpatients (less leave or pass days) by the number of total Medicare discharges for the hospital's most recent complete cost reporting period. Subject to the provisions of paragraphs (e)(3)(ii) through (e)(3)(iv) of this section, the average inpatient length of stay specified under paragraph (e)(2)(ii) of this section is calculated by dividing the total number of days for all patients, including both Medicare and non-Medicare inpatients (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period.

(ii) Effective for cost reporting periods beginning on or after July 1, 2004, in calculating the hospital's average

length of stay, if the days of a stay of an inpatient involves days of care furnished during two or more separate consecutive cost reporting periods, that is, an admission during one cost reporting period and a discharge during a future consecutive cost reporting period, the total number of days of the stay are considered to have occurred in the cost reporting period during which the inpatient was discharged. However, if after application of this provision, a hospital fails to meet the average length of stay specified under paragraphs (e)(2)(i) and (ii) of this section, Medicare will determine the hospital's average inpatient length of stay for cost reporting periods beginning on or after July 1, 2004, but before July 1, 2005, by dividing the applicable total days for Medicare inpatients under paragraph (e)(2)(i) of this section or the total days for all inpatients under paragraph (e)(2)(ii) of this section, during the cost reporting period when they occur, by the number of discharges occurring during the same cost reporting period.

(iii) If a change in a hospital's average length of stay specified under paragraph (e)(2)(i) or paragraph (e)(2)(ii) of this section is indicated, the calculation is made by the same method for the period of at least 5 months of the immediately preceding 6-month period.

(iv) If a hospital has undergone a change of ownership (as described in § 489.18 of this chapter) at the start of a cost reporting period or at any time within the period of at least 5 months of the preceding 6-month period, the hospital may be excluded from the prospective payment system as a long-term care hospital for a cost reporting period if, for the period of at least 5 months of the 6 months immediately preceding the start of the period (including time before the change of ownership), the hospital has the required average length of stay, continuously operated as a hospital, and continuously participated as a hospital in Medicare.

(4) *Rules applicable to new long-term care hospitals*—(i) *Definition*. For purposes of payment under the long-term care hospital prospective payment system under subpart O of this part, a new long-term care hospital is a provider of inpatient hospital services that meets the qualifying criteria in paragraphs (e)(1) and (e)(2) of this section and, under present or previous ownership (or both), its first cost reporting period as a LTCH begins on or after October 1, 2002.

(ii) *Satellite facilities and remote locations of hospitals seeking to become new long-term care hospitals*. Except as specified in paragraph (e)(4)(iii) of this section, a satellite facility (as defined in § 412.22(h)) or a remote location of a hospital (as defined in § 413.65(a)(2) of this chapter) that voluntarily reorganizes as a separate Medicare participating hospital, with or without a concurrent change in ownership, and that seeks to qualify as a new long-term care hospital for Medicare payment purposes must demonstrate through documentation that it meets the average length of stay requirement as specified under paragraphs (e)(2)(i) or (e)(2)(ii) of this section based on discharges that occur on or after the effective date of its participation under Medicare as a separate hospital.

(iii) *Provider-based facility or organization identified as a satellite facility and remote location of a hospital prior to July 1, 2003*. Satellite facilities and remote locations of hospitals that became subject to the provider-based status rules under § 413.65 as of July 1, 2003, that become separately participating hospitals, and that seek to qualify as long-term care hospitals for Medicare payment purposes may submit to the fiscal intermediary discharge data gathered during 5 months of the immediate 6 months preceding the facility's separation from the main hospital for calculation of the average length of stay specified under paragraph (e)(2)(i) or paragraph (e)(2)(ii) of this section.

(f) *Cancer hospitals*—(1) *General rule*. Except as provided in paragraph (f)(2) of this section, if a hospital meets the following criteria, it is classified as a cancer hospital and is excluded from the prospective payment systems beginning with its first cost reporting period beginning on or after October 1, 1989. A hospital classified after December 19, 1989, is excluded beginning with its first cost reporting period beginning after the date of its classification.

(i) It was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983.

(ii) It is classified on or before December 31, 1990, or, if on December 19, 1989, the hospital was located in a State operating a demonstration project under section 1814(b) of the Act, the classification is made on or before December 31, 1991.

(iii) It demonstrates that the entire facility is organized primarily for treatment of and research on cancer (that is, the facility is not a subunit of an acute general hospital or university-based medical center).

(iv) It shows that at least 50 percent of its total discharges have a principal diagnosis that reflects a finding of neoplastic disease. (The principal diagnosis for this purpose is defined as the condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital. For the purposes of meeting this definition, only discharges with ICD–9–CM principal diagnosis codes of 140 through 239, V58.0, V58.1, V66.1, V66.2, or 990 will be considered to reflect neoplastic disease.)

(2) *Alternative.* A hospital that applied for and was denied, on or before December 31, 1990, classification as a cancer hospital under the criteria set forth in paragraph (f)(1) of this section is classified as a cancer hospital and is excluded from the prospective payment systems beginning with its first cost reporting period beginning on or after January 1, 1991, if it meets the criterion set forth in paragraph (f)(1)(i) of this section and the hospital is—

(i) Licensed for fewer than 50 acute care beds as of August 5, 1997;

(ii) Is located in a State that as of December 19, 1989, was not operating a demonstration project under section 1814(b) of the Act; and

(iii) Demonstrates that, for the 4-year period ending on December 31, 1996, at least 50 percent of its total discharges have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(g) *Hospitals outside the 50 States, the District of Columbia, or Puerto Rico.* A hospital is excluded from the prospective payment systems if it is not located in one of the fifty States, the District of Columbia, or Puerto Rico.

(h) *Hospitals reimbursed under special arrangements.* A hospital must be excluded from prospective payment for inpatient hospital services if it is reimbursed under special arrangement as provided in § 412.22(c).

(i) *Changes in classification of hospitals.* For purposes of exclusions from the prospective payment system, the classification of a hospital is effective for the hospital's entire cost reporting period. Any changes in the classification of a hospital are made only at the start of a cost reporting period.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985; 51 FR 22041, June 17, 1986; 51 FR 31496, Sept. 3, 1986; 52 FR 33057, Sept. 1, 1987; 55 FR 36068, Sept. 4, 1990; 55 FR 46887, Nov. 7, 1990; 56 FR 43240, Aug. 30, 1991; 57 FR 39820, Sept. 1, 1992; 59 FR 45396, Sept. 1, 1994; 60 FR 45846, Sept. 1, 1995; 62 FR 46026, Aug. 29, 1997; 66 FR 39933, Aug. 1, 2001; 66 FR 41386, Aug. 7, 2001; 67 FR 56048, Aug. 30, 2002; 68 FR 45469, Aug. 1, 2003; 69 FR 25720, May 7, 2004; 69 FR 25775, May 7, 2004; 69 FR 66976, Nov. 15, 2004]

§ 412.25 Excluded hospital units: Common requirements.

(a) *Basis for exclusion.* In order to be excluded from the prospective payment systems as specified in § 412.1(a)(1) and be paid under the inpatient psychiatric facility prospective payment system as specified in § 412.1(a)(2) or the inpatient rehabilitation facility prospective payment system as specified in § 412.1(a)(3), a psychiatric or rehabilitation unit must meet the following requirements.

(1) Be part of an institution that—

(i) Has in effect an agreement under part 489 of this chapter to participate as a hospital;

(ii) Is not excluded in its entirety from the prospective payment systems; and

(iii) Has enough beds that are not excluded from the prospective payment systems to permit the provision of adequate cost information, as required by § 413.24(c) of this chapter.

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.

(3) Have admission and discharge records that are separately identified

from those of the hospital in which it is located and are readily available.

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.

(5) Meet applicable State licensure laws.

(6) Have utilization review standards applicable for the type of care offered in the unit.

(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds.

(8) Be serviced by the same fiscal intermediary as the hospital.

(9) Be treated as a separate cost center for cost finding and apportionment purposes.

(10) Use an accounting system that properly allocates costs.

(11) Maintain adequate statistical data to support the basis of allocation.

(12) Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date.

(b) *Changes in the size of excluded units.* For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.

(1) *Increase in size.* Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be increased only at the start of a cost reporting period.

(2) *Decrease in size.* Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be decreased at any time during a cost reporting period if the hospital notifies its fiscal intermediary and the CMS Regional Office in writing of the planned decrease at least 30 days before the date of the decrease, and maintains the information needed to accurately determine costs that are attributable to the excluded unit. Any decrease in the number of beds or square footage considered to be part of an excluded unit made during a cost reporting period must remain in effect for the rest of that cost reporting period.

(3) *Exception to changes in square footage and bed size.* The number of beds in an excluded unit may be decreased, and the square footage considered to be part of the unit may be either increased or decreased, at any time, if these changes are made necessary by relocation of a unit—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(c) *Changes in the status of hospital units.* For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.

(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period.

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.

(d) *Number of excluded units.* Each hospital may have only one unit of

each type (psychiatric or rehabilitation) excluded from the prospective payment systems.

(e) *Satellite facilities.* (1) For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

(2) Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of State-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997.

(ii) The satellite facility independently complies with—

(A) For a rehabilitation unit, the requirements under § 412.23(b)(2); or

(B) For a psychiatric unit, the requirements under § 412.27(a).

(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.

(D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.

(E) It is treated as a separate cost center of the hospital unit of which it is a part.

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.

(3) Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999.

(4) In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility as of September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility at any time, if these changes are made necessary by relocation of the facility—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(5) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003.

(f) *Changes in classification of hospital units.* For purposes of exclusions from

the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period.

(g) *CAH units not meeting applicable requirements.* If a psychiatric or rehabilitation unit of a CAH does not meet the requirements of § 485.647 with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39820, Sept. 1, 1992; 58 FR 46337, Sept. 1, 1993; 59 FR 45400, Sept. 1, 1994; 64 FR 41540, July 30, 1999; 66 FR 39933, Aug. 1, 2001; 66 FR 41387, Aug. 7, 2001; 67 FR 50111, Aug. 1, 2002; 68 FR 45469 and 45698, Aug. 1, 2003; 69 FR 49241, Aug. 11, 2004; 69 FR 66976, Nov. 15, 2004; 70 FR 47952, Aug. 15, 2005]

§ 412.27 Excluded psychiatric units: Additional requirements.

In order to be excluded from the prospective payment system as specified in § 412.1(a)(1), and paid under the prospective payment system as specified in § 412.1(a)(2), a psychiatric unit must meet the following requirements:

(a) Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the Fourth Edition, Text Revision of the American Psychiatric Association's Diagnostic and Statistical Manual, or in Chapter Five (''Mental Disorders'') of the International Classification of Diseases, Ninth Revision, Clinical Modification.

(b) Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, occupational therapy, and recreational therapy.

(c) Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

(1) *Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.

(i) The identification data must include the inpatient's legal status.

(ii) A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(iii) The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.

(iv) The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(v) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(2) *Psychiatric evaluation.* Each inpatient must receive a psychiatric evaluation that must—

(i) Be completed within 60 hours of admission;

(ii) Include a medical history;

(iii) Contain a record of mental status;

(iv) Note the onset of illness and the circumstances leading to admission;

(v) Describe attitudes and behavior;

(vi) Estimate intellectual functioning, memory functioning, and orientation; and

(vii) Include an inventory of the inpatient's assets in descriptive, not interpretative fashion.

(3) *Treatment plan.*

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis; short-term

and long-term goals; the specific treatment modalities utilized; the responsibilities of each member of the treatment team; and adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out; and

(ii) The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included.

(4) *Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient, a nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.

(5) *Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

(d) Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning, as follows:

(1) *Personnel.* The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—

(i) Evaluate inpatients;

(ii) Formulate written, individualized, comprehensive treatment plans;

(iii) Provide active treatment measures; and

(iv) Engage in discharge planning.

(2) *Director of inpatient psychiatric services: Medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(i) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(ii) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(3) *Nursing services.* The unit must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient.

(i) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(ii) The staffing pattern must ensure the availability of a registered nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program.

(4) *Psychological services.* The unit must provide or have available psychological services to meet the needs of the inpatients. The services must be

furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.

(5) *Social services*. There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures. Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(6) *Therapeutic activities*. The unit must provide a therapeutic activities program.

(i) The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(ii) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39820, Sept. 1, 1992; 59 FR 45397, 45400, Sept. 1, 1994; 69 FR 66976, Nov. 15, 2004]

§ 412.29 Excluded rehabilitation units: Additional requirements.

In order to be excluded from the prospective payment systems described in § 412.1(a)(1) and to be paid under the prospective payment system specified in § 412.1(a)(3), a rehabilitation unit must meet the following requirements:

(a) Have met either the requirements for—

(1) New units under § 412.30(a); or

(2) Converted units under § 412.30(c).

(b) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech therapy, social services or psychological services, and orthotic and prosthetic services.

(d) Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

(e) Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment, and that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(f) Have a director of rehabilitation who—

(1) Provides services to the unit and to its inpatients for at least 20 hours per week;

(2) Is a doctor of medicine or osteopathy;

(3) Is licensed under State law to practice medicine or surgery; and

(4) Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39821, Sept. 1, 1992; 59 FR 45397, 45400, Sept. 1, 1994; 60 FR 45847, Sept. 1, 1995; 66 FR 41387, Aug. 7, 2001; 68 FR 45699, Aug. 1, 2003; 69 FR 66976, Nov. 15, 2004]

§ 412.30 Exclusion of new rehabilitation units and expansion of units already excluded.

(a) *Bed capacity in units*. A decrease in bed capacity must remain in effect for at least a full 12-month cost reporting period before an equal or lesser number of beds can be added to the hospital's licensure and certification and considered ''new'' under paragraph (b) of this section. Thus, when a hospital seeks to establish a new unit under the criteria under paragraph (b) of this section, or to enlarge an existing unit under the criteria under paragraph (d) of this section, the regional office will review its records on the facility to determine whether any beds have been delicensed and decertified

during the 12-month cost reporting period before the period for which the hospital seeks to add the beds. To the extent bed capacity was removed from the hospital's licensure and certification during that period, that amount of bed capacity may not be considered ''new'' under paragraph (b) of this section.

(b) *New units.* (1) A hospital unit is considered a new unit if the hospital—

(i) Has not previously sought exclusion for any rehabilitation unit; and

(ii) Has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit.

(2) A hospital that seeks exclusion of a new rehabilitation unit may provide a written certification that the inpatient population the hospital intends the unit to serve meets the requirements of § 412.23(b)(2) instead of showing that the unit has treated such a population during the hospital's most recent cost reporting period.

(3) The written certification described in paragraph (b)(2) of this section is effective for the first full cost reporting period during which the unit is used to provide hospital inpatient care.

(4) If a hospital that has not previously participated in the Medicare program seeks exclusion of a rehabilitation unit, it may designate certain beds as a new rehabilitation unit for the first full 12-month cost reporting period that occurs after it becomes a Medicare-participating hospital. The written certification described in paragraph (b)(2) of this section also is effective for any cost reporting period of not less than 1 month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period.

(5) A hospital that has undergone a change of ownership or leasing as defined in § 489.18 of this chapter is not considered to have participated previously in the Medicare program.

(c) *Converted units.* A hospital unit is considered a converted unit if it does not qualify as a new unit under paragraph (a) of this section. A converted unit must have treated, for the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), an inpatient population meeting the requirements of § 412.23(b)(2).

(d) *Expansion of excluded rehabilitation units.*—(1) *New bed capacity.* The beds that a hospital seeks to add to its excluded rehabilitation unit are considered new beds only if—

(i) The hospital's State-licensed and Medicare-certified bed capacity increases at the start of the cost reporting period for which the hospital seeks to increase the size of its excluded rehabilitation unit, or at any time after the start of the preceding cost reporting period; and

(ii) The hospital has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds it seeks to add to the unit.

(2) *Conversion of existing bed capacity.* (i) Bed capacity is considered to be existing bed capacity if it does not meet the definition of new bed capacity under paragraph (d)(1) of this section.

(ii) A hospital may increase the size of its excluded rehabilitation unit through the conversion of existing bed capacity only if it shows that, for the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), the beds have been used to treat an inpatient population meeting the requirements of § 412.23(b)(2).

(e) *Retroactive adjustments for certain units.* For cost reporting periods beginning on or after October 1, 1991, if a hospital has a new rehabilitation unit excluded from the prospective payment systems for a cost reporting period under paragraph (a) of this section or expands an existing rehabilitation unit under paragraph (c) of this section, but the inpatient population actually treated in the new unit or the beds added to the existing unit during that cost reporting period does not meet the

requirements in § 412.23(b)(2), CMS adjusts payments to the hospital retroactively in accordance with the provisions in § 412.130 of this part.

[50 FR 12741, Mar. 29, 1985, as amended at 56 FR 43420, Aug. 30, 1991; 57 FR 39821, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994; 60 FR 45847, Sept. 1, 1995; 62 FR 46027, Aug. 29, 1997; 68 FR 45699, Aug. 1, 2003; 69 FR 25776, May 7, 2004]

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

§ 412.40 General requirements.

(a) A hospital must meet the conditions of this subpart to receive payment under the prospective payment systems for inpatient hospital services furnished to Medicare beneficiaries.

(b) If a hospital fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare beneficiaries, CMS may, as appropriate—

(1) Withhold Medicare payment (in full or in part) to the hospital until the hospital provides adequate assurances of compliance; or

(2) Terminate the hospital's provider agreement.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39821, Sept. 1, 1992]

§ 412.42 Limitations on charges to beneficiaries.

(a) *Prohibited charges.* A hospital may not charge a beneficiary for any services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment systems.

(b) *Permitted charges—Stay covered.* A hospital receiving payment under the prospective payment systems for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the following:

(1) The applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter.

(2) Noncovered items and services, furnished at any time during a covered stay, unless they are excluded from coverage only on the basis of the following:

(i) The exclusion of custodial care under § 405.310(g) of this chapter (see paragraph (c) of this section for when charges may be made for custodial care).

(ii) The exclusion of medically unnecessary items and services under § 405.310(k) of this chapter (see paragraphs (c) and (d) of this section for when charges may be made for medically unnecessary items and services).

(iii) The exclusion under § 405.310(m) of this chapter of nonphysician services furnished to hospital inpatients by other than the hospital or a provider or supplier under arrangements made by the hospital.

(iv) The exclusion of items and services furnished when the patient is not entitled to Medicare Part A benefits under subpart A of part 406 of this chapter (see paragraph (e) of this section for when charges may be made for items and services furnished when the patient is not entitled to benefits).

(v) The exclusion of items and services furnished after Medicare Part A benefits are exhausted under § 409.61 of this chapter (see paragraph (e) of this section for when charges may be made for items and services furnished after benefits are exhausted).

(c) *Custodial care and medically unnecessary inpatient hospital care.* A hospital may charge a beneficiary for services excluded from coverage on the basis of § 411.15(g) of this chapter (custodial care) or § 411.15(k) of this chapter (medically unnecessary services) and furnished by the hospital after all of the following conditions have been met:

(1) The hospital (acting directly or through its utilization review committee) determines that the beneficiary no longer requires inpatient hospital care. (The phrase ''inpatient hospital care'' includes cases where a beneficiary needs a SNF level of care, but, under Medicare criteria, a SNF-level bed is not available. This also means that a hospital may find that a patient awaiting SNF placement no longer requires inpatient hospital care

because either a SNF-level bed has become available or the patient no longer requires SNF-level care.)

(2) The attending physician agrees with the hospital's determination in writing (for example, by issuing a written discharge order). If the hospital believes that the beneficiary does not require inpatient hospital care but is unable to obtain the agreement of the physician, it may request an immediate review of the case by the QIO. Concurrence by the QIO in the hospital's determination will serve in lieu of the physician's agreement.

(3) The hospital (acting directly or through its utilization review committee) notifies the beneficiary (or person acting on his or her behalf) in writing that—

(i) In the hospital's opinion, and with the attending physician's concurrence or that of the QIO, the beneficiary no longer requires inpatient hospital care;

(ii) Customary charges will be made for continued hospital care beyond the second day following the date of the notice;

(iii) The QIO will make a formal determination on the validity of the hospital's finding if the beneficiary remains in the hospital after he or she is liable for charges;

(iv) The determination of the QIO made after the beneficiary received the purportedly noncovered services will be appealable by the hospital, the attending physician, or the beneficiary under the appeals procedures that apply to QIO determinations affecting Medicare Part A payment; and

(v) The charges for continued care will be invalid and refunded if collected by the hospital, to the extent that a finding is made that the beneficiary required continued care beyond the point indicated by the hospital.

(4) If the beneficiary remains in the hospital after the appropriate notification, and the hospital, the physician who concurred in the hospital determination on which the notice was based, or QIO subsequently finds that the beneficiary requires an acute level of inpatient hospital care, the hospital may not charge the beneficiary for continued care until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence, and notifies the beneficiary, as required in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(d) *Medically unnecessary diagnostic and therapeutic services.* A hospital may charge a beneficiary for diagnostic procedures and studies, and therapeutic procedures and courses of treatment (for example, experimental procedures) that are excluded from coverage under § 405.310(k) of this chapter (medically unnecessary items and services), even though the beneficiary requires continued inpatient hospital care, if those services are furnished after the beneficiary (or the person acting on his or her behalf) has acknowledged in writing that the hospital (acting directly or through its utilization review committee and with the concurrence of the intermediary) has informed him or her as follows:

(1) In the hospital's opinion, which has been agreed to by the intermediary, the services to be furnished are not considered reasonable and necessary under Medicare.

(2) Customary charges will be made if he or she receives the services.

(3) If the beneficiary receives the services, a formal determination on the validity of the hospital's finding is made by the intermediary and, to the extent that the decision requires the exercise of medical judgment, the QIO.

(4) The determination is appealable by the hospital, the attending physician, or the beneficiary under the appeals procedure that applies to determinations affecting Medicare Part A payment.

(5) The charges for the services will be invalid and, to the extent collected, will be refunded by the hospital if the services are found to be covered by Medicare.

(e) *Services furnished on days when the individual is not entitled to Medicare Part A benefits or has exhausted the available benefits.* The hospital may charge the beneficiary its customary charges for noncovered items and services furnished on outlier days (as described in Subpart F of this part) for which payment is denied because the beneficiary is not entitled to Medicare Part A or his or her Medicare Part A benefits are exhausted. (1) If payment is considered

for outlier days, the entire stay is reviewed and days up to the number of days in excess of the outlier threshold may be denied on the basis of nonentitlement to Part A or exhaustion of benefits. (2) In applying this rule, the latest days will be denied first.

(f) *Differential for private room or other luxury services.* The hospital may charge the beneficiary the customary charge differential for a private room or other luxury service that is more expensive than is medically required and is furnished for the personal comfort of the beneficiary at his or her request (or the request of the person acting on his or her behalf).

(g) *Review.* (1) The QIO or intermediary may review any cases in which the hospital advises the beneficiary (or the person acting on his or her behalf) of the noncoverage of the services in accordance with paragraph (c)(3) or (d) of this section.

(2) The hospital must identify such cases to the QIO or intermediary in accordance with CMS instructions.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985; 54 FR 41747, Oct. 11, 1989; 57 FR 39821, Sept. 1, 1992]

§ 412.44 Medical review requirements: Admissions and quality review.

Beginning on November 15, 1984, a hospital must have an agreement with a QIO to have the QIO review, on an ongoing basis, the following:

(a) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges.

(b) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter.

(c) The validity of the hospital's diagnostic and procedural information.

(d) The completeness, adequacy, and quality of the services furnished in the hospital.

(e) Other medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

[50 FR 15326, Apr. 17, 1985, as amended at 50 FR 35689, Sept. 3, 1985; 50 FR 41886, Oct. 16, 1985]

§ 412.46 Medical review requirements: Physician acknowledgement.

(a) *Basis.* Because payment under the prospective payment system is based in part on each patient's principal and secondary diagnoses and major procedures performed, as evidenced by the physician's entries in the patient's medical record, physicians must complete an acknowledgement statement to this effect.

(b) *Content of physician acknowledgement statement.* When a claim is submitted, the hospital must have on file a signed and dated acknowledgement from the attending physician that the physician has received the following notice:

Notice to Physicians: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

(c) *Completion of acknowledgement.* The acknowledgement must be completed by the physician at the time that the physician is granted admitting privileges at the hospital, or before or at the time the physician admits his or her first patient. Existing acknowledgements signed by physicians already on staff remain in effect as long as the physician has admitting privileges at the hospital.

[60 FR 45847, Sept. 1, 1995]

§ 412.48 Denial of payment as a result of admissions and quality review.

(a) If CMS determines, on the basis of information supplied by a QIO that a hospital has misrepresented admissions, discharges, or billing information, or has taken an action that results in the unnecessary admission of an individual entitled to benefits under Part A, unnecessary multiple admissions of an individual, or other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries, CMS may as appropriate—

(1) Deny payment (in whole or in part) under Part A with respect to inpatient hospital services provided with respect to such an unnecessary admission or subsequent readmission of an individual; or

(2) Require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(b) When payment with respect to admission of an individual patient is denied by a QIO under paragraph (a)(1) of this section, and liability is not waived in accordance with §§ 405.330 through 405.332 of this chapter, notice and appeals are provided under procedures established by CMS to implement the provisions of section 1155 of the Act, Right to Hearing and Judicial Review.

(c) A determination under paragraph (a) of this section, if it is related to a pattern of inappropriate admissions and billing practices that has the effect of circumventing the prospective payment systems, is referred to the Department's Office of Inspector General, for handling in accordance with § 1001.301 of this title.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, 35689, Sept. 3, 1985; 51 FR 34787, Sept. 30, 1986; 57 FR 39821, Sept. 1, 1992]

§ 412.50 Furnishing of inpatient hospital services directly or under arrangements.

(a) The applicable payments made under the prospective payment systems, as described in subparts H and M of this part, are payment in full for all inpatient hospital services, as defined in § 409.10 of this chapter. Inpatient hospital services do not include the following types of services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in § 410.69 of this chapter.

(b) CMS does not pay any provider or supplier other than the hospital for services furnished to a beneficiary who is an inpatient, except for the services described in paragraphs (a)(1) through (a)(6) of this section.

(c) The hospital must furnish all necessary covered services to the beneficiary either directly or under arrangements (as defined in § 409.3 of this chapter).

[50 FR 12741, Mar. 29, 1985, as amended at 53 FR 38527, Sept. 30, 1988; 57 FR 39821, Sept. 1, 1992; 60 FR 63188, Dec. 8, 1995; 65 FR 18537, Apr. 7, 2000]

§ 412.52 Reporting and recordkeeping requirements.

All hospitals participating in the prospective payment systems must meet the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 57 FR 39821, Sept. 1, 1992]

Subpart D—Basic Methodology for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

§ 412.60 DRG classification and weighting factors.

(a) *Diagnosis-related groups.* CMS establishes a classification of inpatient hospital discharges by Diagnosis-Related Groups (DRGs).

(b) *DRG weighting factors.* CMS assigns, for each DRG, an appropriate weighting factor that reflects the estimated relative cost of hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups.

(c) *Assignment of discharges to DRGs.* CMS establishes a methodology for classifying specific hospital discharges within DRGs which ensures that each hospital discharge is appropriately assigned to a single DRG based on essential data abstracted from the inpatient bill for that discharge.

(1) The classification of a particular discharge is based, as appropriate, on the patient's age, sex, principal diagnosis (that is, the diagnosis established

after study to be chiefly responsible for causing the patient's admission to the hospital), secondary diagnoses, procedures performed, and discharge status.

(2) Each discharge is assigned to only one DRG (related, except as provided in paragraph (c)(3) of this section, to the patient's principal diagnosis) regardless of the number of conditions treated or services furnished during the patient's stay.

(3) When the discharge data submitted by a hospital show a surgical procedure unrelated to a patient's principal diagnosis, the bill is returned to the hospital for validation and reverification. CMS's DRG classification system provides a DRG, and an appropriate weighting factor, for the group of cases for which the unrelated diagnosis and procedure are confirmed.

(d) *Review of DRG assignment.* (1) A hospital has 60 days after the date of the notice of the initial assignment of a discharge to a DRG to request a review of that assignment. The hospital may submit additional information as a part of its request.

(2) The intermediary reviews the hospital's request and any additional information and decides whether a change in the DRG assignment is appropriate. If the intermediary decides that a higher-weighted DRG should be assigned, the case will be reviewed by the appropriate QIO as specified in § 466.71(c)(2) of this chapter.

(3) Following the 60-day period described in paragraph (d)(1) of this section, the hospital may not submit additional information with respect to the DRG assignment or otherwise revise its claim.

(e) *Revision of DRG classification and weighting factors.* Beginning with discharges in fiscal year 1988, CMS adjusts the classifications and weighting factors established under paragraphs (a) and (b) of this section at least annually to reflect changes in treatment patterns, technology, and other factors that may change the relative use of hospital resources.

[50 FR 12741, Mar. 29, 1985, as amended at 52 FR 33057, Sept. 1, 1987; 57 FR 39821, Sept. 1, 1992; 59 FR 45397, Sept. 1, 1994]

§ 412.62 Federal rates for inpatient operating costs for fiscal year 1984.

(a) *General rule.* CMS determines national adjusted DRG prospective payment rates for operating costs, for each inpatient hospital discharge in fiscal year 1984 involving inpatient hospital services of a hospital in the United States subject to the prospective payment system under subpart B of this part, and determines regional adjusted DRG prospective payment rates for inpatient operating costs for such discharges in each region, for which payment may be made under Medicare Part A. Such rates are determined for hospitals located in urban or rural areas within the United States and within each such region, respectively, as described in paragraphs (b) through (k) of this section.

(b) *Determining allowable individual hospital inpatient operating costs.* CMS determines the Medicare allowable operating costs per discharge of inpatient hospital services for each hospital in the data base for the most recent cost reporting period for which data are available.

(c) *Updating for fiscal year 1984.* CMS updates each amount determined under paragraph (b) of this section for fiscal year 1984 by—

(1) Updating for fiscal year 1983 by the estimated average rate of change of hospital costs industry-wide between the cost reporting period used under paragraph (b) of this section and fiscal year 1983; and

(2) Projecting for fiscal year 1984 by the applicable percentage increase in the hospital market basket for fiscal year 1984.

(d) *Standardizing amounts.* CMS standardizes the amount updated under paragraph (c) of this section for each hospital by—

(1) Adjusting for area variations in case mix among hospitals;

(2) Excluding an estimate of indirect medical education costs;

(3) Adjusting for area variations in hospital wage levels; and

(4) Adjusting for the effects of a higher cost of living for hospitals located in Alaska and Hawaii.

(e) *Computing urban and rural averages.* CMS computes an average of the standardized amounts determined

under paragraph (d) of this section for urban and rural hospitals in the United States and for urban and rural hospitals in each region.

(f) *Geographic classifications.* (1) For purposes of paragraph (e) of this section, the following definitions apply:

(i) The term *region* means one of the nine census divisions, comprising the fifty States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes.

(ii) The term *urban area* means—

(A) A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or

(B) The following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

(iii) The term *rural area* means any area outside an urban area.

(iv) The phrase *hospital reclassified as rural* means a hospital located in a county that was part of an MSA or NECMA, as defined by the Executive Office of Management and Budget, but is not part of an MSA or NECMA as a result of an Executive Office of Management and Budget redesignation occurring after April 20, 1983.

(2) For hospitals within an MSA or NECMA that crosses census division boundaries, the following provisions apply:

(i) The MSA or NECMA is deemed to belong to the census division in which most of the hospitals within the MSA or NECMA are located.

(ii) If a hospital would receive a lower Federal rate because most of the hospitals are located in a census division with a lower Federal rate than the rate applicable to the census division in which the hospital is located, the payment rate will not be reduced for the hospital's cost reporting period beginning before October 1, 1984.

(iii) If an equal number of hospitals within the MSA or NECMA are located in each census division, such hospitals are deemed to be in the census division with the higher Federal rate.

(g) *Adjusting the average standardized amounts.* CMS adjusts each of the average standardized amounts determined under paragraphs (c), (d), and (e) of this section by factors representing CMS's estimates of the following:

(1) The amount of payment that would have been made under Medicare Part B for nonphysician services to hospital inpatients during the first cost reporting period subject to prospective payment were it not for the fact that such services must be furnished either directly by hospitals or under arrangements in order for any Medicare payment to be made after September 30, 1983 (the effective date of § 405.310(m) of this chapter).

(2) The amount of FICA taxes that would be incurred during the first cost reporting period subject to the prospective payment system, by hospitals that had not incurred such taxes for any or all of their employees during the base period described in paragraph (c) of this section.

(h) *Reducing for value of outlier payments.* CMS reduces each of the adjusted average standardized amounts determined under paragraphs (c) through (g) of this section by a proportion equal to the proportion (estimated by CMS) of the total amount of payments based on DRG prospective payment rates that are additional payments for outlier cases under subpart F of this part.

(i) *Maintaining budget neutrality.* (1) CMS adjusts each of the reduced standardized amounts determined under paragraphs (c) through (h) of this section as required for fiscal year 1984 so that the estimated amount of aggregate payments made, excluding the hospital-specific portion (that is, the total of the Federal portion of transition payments, plus any adjustments and special treatment of certain classes of hospitals for Federal fiscal year 1984) is not greater or less than 25 percent of the payment amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1984 under the Social Security Act as in effect on April 19, 1983.

(2) The aggregate payments considered under this paragraph exclude payments for per case review by a utilization and quality control quality improvement organization, as allowed under section 1866(a)(1)(F) of the Act.

(j) *Computing Federal rates for inpatient operating costs for urban and rural hospitals in the United States and in each region.* For each discharge classified within a DRG, CMS establishes a national prospective payment rate for inpatient operating costs and a regional prospective payment rate for inpatient operating costs for each region, as follows:

(1) For hospitals located in an urban area in the United States or in that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraphs (c) through (i) of this section) for hospitals located in an urban area in the United States or in that region; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(2) For hospitals located in a rural area in the United States or in that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraphs (c) through (i) of this section) for hospitals located in a rural area in the United States or that region; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(k) *Adjusting for different area wage levels.* CMS adjusts the proportion (as estimated by CMS from time to time) of Federal rates computed under paragraph (j) of this section that are attributable to wages and labor-related costs, for area differences in hospital wage levels by a factor (established by CMS) reflecting the relative hospital wage level in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (f) of this section) of the hospital compared to the national average hospital wage level.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 53 FR 38527, Sept. 30, 1988; 57 FR 39821, Sept. 1, 1992; 58 FR 46337, Sept. 1, 1993]

§ 412.63 Federal rates for inpatient operating costs for Federal fiscal years 1984 through 2004.

(a) *General rule.* (1) CMS determines a national adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge in Federal fiscal years 1985 through 2004 involving inpatient hospital service of a hospital in the United States, subject to the PPS, and determines a regional adjusted PPS rate for operating costs for such discharges in each region for which payment may be made under Medicare Part A.

(2) Each such rate is determined for hospitals located in urban or rural areas within the United States and within each such region, respectively, as described under paragraphs (b) through (u) of this section.

(b) *Geographic classifications.* Effective for fiscal years 1985 through 2004, the following rules apply.

(1) For purposes of this section, the definitions set forth in § 412.62(f) apply, except that, effective January 1, 2000, a hospital reclassified as rural may mean a reclassification that results from a geographic redesignation as set forth in § 412.62(f)(1)(iv) or a reclassification that results from an urban hospital applying for reclassification as rural as set forth in § 412.103.

(2) For hospitals within an MSA or NECMA that crosses census division boundaries, the following provisions apply:

(i) The MSA or NECMA is deemed to belong to the census division in which most of the hospitals within the MSA or NECMA are located.

(ii) A hospital that met the conditions specified in § 412.62(f)(2)(ii) and therefore did not receive a lower Federal rate that would have applied for cost reporting periods beginning before October 1, 1984, receives the lower Federal rate applicable to all hospitals in the MSA or NECMA in which it is located effective with the hospital's cost reporting period that begins on or after October 1, 1984.

(iii) The higher Federal rate is payable to all hospitals in the MSA or NECMA if an equal number of hospitals within the MSA or NECMA are located in each census division.

(3) For discharges occurring on or after October 1, 1988, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greater number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs or NECMAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs or NECMAs. These EOMB standards are set forth in the notice of final standards for classification of MSAs published in the FEDERAL REGISTER on January 3, 1980 (45 FR 956), and available from CMS, East High Rise Building, room 132, 6325 Security Boulevard, Baltimore, Maryland 21207.

(4) For purposes of this section, any change in an MSA or NECMA designation is recognized on the October 1 following the effective date of the change.

(5) For discharges occurring on or after October 1, 1988, for hospitals that consist of two or more separately located inpatient hospital facilities the national adjusted prospective payment rate is based on the geographic location of the hospital facility at which the discharge occurs.

(c) *Updating previous standardized amounts.* (1) For discharges occurring in fiscal year 1985 through fiscal year 2003, CMS computes average standardized amounts for hospitals in urban areas and rural areas within the United States, and in urban areas and rural areas within each region. For discharges occurring in fiscal year 2004, CMS computes an average standardized amount for hospitals located in all areas.

(2) Each of those amounts is equal to the respective adjusted average standardized amount computed for fiscal year 1984 under § 412.62(g)—

(i) Increased for fiscal year 1985 by the applicable percentage increase in the hospital market basket;

(ii) Adjusted by the estimated amount of Medicare payment for nonphysician services furnished to hospital inpatients that would have been paid under Part B were it not for the fact that such services must be furnished either directly by hospitals or under arrangements;

(iii) Reduced by a proportion equal to the proportion (estimated by CMS) of the total amount of prospective payments that are additional payment amounts attributable to outlier cases under subpart F of this part; and

(iv) Adjusted for budget neutrality under paragraph (h) of this section.

(3) For fiscal year 1986 and thereafter. CMS computes, for urban and rural hospitals in the United States and for urban and rural hospitals in each region, average standardized amount equal to the respective adjusted average standardized amounts computed for the previous fiscal year—

(i) Increased by the applicable percentage increase determined under paragraphs (d) through (g) of this section;

(ii) Adjusted by the estimated amount of Medicare payment for nonphysician services furnished to hospital inpatients that would have been paid under Part B were it not for the fact that such services must be furnished either directly by hospitals or under arrangements; and

(iii) For discharges occurring on or after October 1, 1985 and before October 1, 1986, reduced by a proportion (estimated by CMS) of the amount of payments based on the total amount of prospective payments that are additional payment amounts attributable to outlier cases under subpart F of this part, and for discharges occurring on or after October 1, 1986, reduced by a proportion (estimated by CMS) of the amount of payments that, based on the total amount of prospective payments for urban hospitals and the total amount of prospective payments for rural hospitals, are additional payments attributable to outlier cases in such hospitals under subpart F of this part.

(4) For fiscal years 1987 through 1990 CMS standardizes the average standardized amounts by excluding an estimate of the payments for hospitals that serve a disproportionate share of low-income patients.

(5) For fiscal years 1987 through 2004, CMS standardizes the average standardized amounts by excluding an estimate of indirect medical education payments.

(6) For fiscal years 1988 through 2003, CMS computes average standardized amounts for hospitals located in large urban areas, other urban areas, and rural areas. The term *large urban area* means an MSA with a population of more than 1,000,000 or an NECMA, with a population of more than 970,000 based on the most recent available population data published by the Census Bureau. For fiscal year 2004, CMS computes an average standardized amount for hospitals located in all areas.

(d) *Applicable percentage change for fiscal year 1986*. (1) The applicable percentage change for fiscal year 1986 is—

(i) For discharges occurring on or after October 1, 1985 and before May 1. 1986, zero percent; and

(ii) For discharges occurring on or after May 1, 1986, one-half of one percent.

(2) For purposes of determining the standardized amounts for discharges occurring on or after October 1, 1986, the applicable percentage increase for fiscal year 1986 is deemed to have been one-half of one percent.

(e) *Applicable percentage change for fiscal year 1987*. The applicable percentage change for fiscal year 1987 is 1.15 percent.

(f) *Applicable percentage change for fiscal year 1988*. (1) The applicable percentage change for fiscal year 1988 is—

(i) For discharges occurring on or after October 1, 1987 and before November 21, 1987, zero percent;

(ii) For discharges occurring on or after November 21, 1987 and before April 1, 1988, 2.7 percent; and

(iii) For discharges occurring on or after April 1, 1988 and before October 1, 1988—

(A) 3.0 percent for hospitals located in rural areas;

(B) 1.5 percent for hospitals located in large urban areas; and

(C) 1.0 percent for hospitals located in other urban areas.

(2) For purposes of determining the standardized amounts for discharges occurring on or after October 1, 1988 (for Federal fiscal year 1989), the applicable percentage change for fiscal year 1988 is deemed to have been—

(i) 3.0 percent for hospitals located in rural areas;

(ii) 1.5 percent for hospitals located in large urban areas; and

(iii) 1.0 percent for hospitals located in other urban areas.

(g) *Applicable percentage change for fiscal year 1989*. The applicable percentage change for fiscal year 1989 is the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter)—

(1) Minus 1.5 percentage points for hospitals located in rural areas;

(2) Minus 2.0 percentage points for hospitals in large urban areas; and

(3) Minus 2.5 percentage points for hospitals in other urban areas.

(h) *Applicable percentage change for fiscal year 1990*. (1) The applicable percentage change for fiscal year 1990 is—

(i) For discharges occurring on or after October 1, 1989 and before January 1, 1990, 5.5 percent; and

(ii) For discharges occurring on or after January 1, 1990 and before October 1, 1990—

(A) 9.72 percent for hospitals located in rural areas;

(B) 5.62 percent for hospitals located in large urban areas; and

(C) 4.97 percent for hospitals located in other urban areas.

(2) For purposes of determining the standardized amounts for discharges occurring on or after October 1, 1990, the applicable percentage change for fiscal year 1990 is deemed to have been the percentage change provided for in paragraph (h)(1)(ii) of this section.

(i) *Applicable percentage change for fiscal year 1991*. (1) The applicable percentage change for fiscal year 1991 is—

(i) For discharges occurring on or after October 1, 1990 and before October 21, 1990, 5.2 percent;

(ii) For discharges occurring on or after October 21, 1990 and before January 1, 1991, 0.0 percent; and

(iii) For discharges occurring on or after January 1, 1991 and before October 1, 1991—

(A) 4.5 percent for hospitals located in rural areas; and

(B) 3.2 percent for hospitals located in large urban areas and other urban areas.

(2) For purposes of determining the standardized amounts for discharges occurring on or after October 1, 1991, the applicable percentage change for fiscal year 1991 is deemed to have been the percentage change provided for in paragraph (i)(1)(iii) of this section.

(j) *Applicable percentage change for fiscal year 1992.* The applicable percentage change for fiscal year 1992 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a)(3) of this chapter)—

(1) Minus 0.6 percentage points for hospitals located in rural areas.

(2) Minus 1.6 percentage points for hospitals located in large urban areas and other urban areas.

(k) *Applicable percentage change for fiscal year 1993.* The applicable percentage change for fiscal year 1993 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a)(3) of this chapter)—

(1) Minus 0.55 percentage points for hospitals located in rural areas.

(2) Minus 1.55 percentage points for hospitals located in large urban areas and other urban areas.

(l) *Applicable percentage change for fiscal year 1994.* The applicable percentage change for fiscal year 1994 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter)—

(1) Minus 1.0 percentage point for hospitals located in rural areas.

(2) Minus 2.5 percentage points for hospitals located in large urban areas and other urban areas.

(m) *Applicable percentage change for fiscal year 1995.* The applicable percentage change for fiscal year 1995 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter)—

(1) Plus, for hospitals located in rural areas, the percentage increase necessary so that the average standardized amounts computed under paragraph (c) through (i) of this section are equal to the average standardized amounts for hospitals located in an urban area other than a large urban area.

(2) Minus 2.5 percentage points for hospitals located in large urban areas and other urban areas.

(n) *Applicable percentage change for fiscal year 1996.* The applicable percentage change for fiscal year 1996 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) minus 2.0 percentage points for all areas.

(o) *Applicable percentage change for fiscal year 1997.* The applicable percentage change for fiscal year 1997 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) minus 0.5 percentage point for all areas.

(p) *Applicable percentage change for fiscal year 1998.* The applicable percentage change for fiscal year 1998 is 0 percent for hospitals in all areas.

(q) *Applicable percentage change for fiscal year 1999.* The applicable percentage change for fiscal year 1999 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) minus 1.9 percentage points for hospitals in all areas.

(r) *Applicable percentage change for fiscal year 2000.* The applicable percentage change for fiscal year 2000 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) minus 1.8 percentage points for hospitals in all areas.

(s) *Applicable percentage change for fiscal year 2001.* The applicable percentage change for discharges occurring in fiscal year 2001 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas as follows:

(1) For discharges occurring on October 1, 2000 or before April 1, 2001 the percentage increase in the market basket index for prospective payment hospitals (as defined in § 41340(a) of this subchapter) for sole community hospitals and the increase in the market basket index minus 1.1 percentage points for other hospitals in all areas; and

(2) For discharges occurring on April 1, 2001 or before October 1, 2001 the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for sole community hospitals and the increase in the market basket index plus 1.1 percentage points for other hospitals in all areas.

(t) *Applicable percentage change for fiscal years 2002 and 2003.* The applicable percentage change for fiscal years 2002 and 2003 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) minus 0.55 percentage points for hospitals in all areas.

(u) *Applicable percentage change for fiscal year 2004.* The applicable percentage change for fiscal year 2004 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

(v) *Maintaining budget neutrality for fiscal year 1985.* (1) For fiscal year 1985, CMS will adjust each of the reduced standardized amounts determined under paragraph (c) of this section as required for fiscal year 1985 to ensure that the estimated amount of aggregate payments made, excluding the hospital-specific portion (that is, the total of the Federal portion of transition payments, plus any adjustments and special treatment of certain classes of hospitals for fiscal year 1985) is not greater or less than 50 percent of the payment amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1985 under the law as in effect on April 19, 1983.

(2) The aggregate payments considered under this paragraph exclude payments for per case review by a utilization and quality control quality improvement organization, as allowed under section 1866(a)(1)(F) of the Act.

(w) *Computing Federal rates for inpatient operating costs for hospitals located in large urban and other areas.* For each discharge classified within a DRG, CMS establishes for the fiscal year a national prospective payment rate and a regional prospective payment rate for inpatient operating costs, for each region, as follows:

(1) For hospitals located in a large urban area in the United States or that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in a large urban area in the United States or in that region; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(2) For hospitals located in an other area in the United States or that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in an other area in the United States or that region; and

(ii) The weighting factor (determined under § 412.60(b)) for that DRG.

(x) *Adjusting for different area wage levels.* (1) CMS adjusts the proportion (as estimated by CMS from time to time) of Federal rates for inpatient operating costs computed under paragraph (j) of this section that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the national average level of hospital wages and wage-related costs. The wage index is updated annually.

(2)(i) CMS makes a midyear correction to the wage index for an area only if a hospital can show that—

(A) The intermediary or CMS made an error in tabulating its data; and

(B) The hospital could not have known about the error, or did not have the opportunity to correct the error, before the beginning of the Federal fiscal year.

(ii) A midyear correction to the wage index is effective prospectively from the date the change is made to the wage index.

(3) If a judicial decision reverses a CMS denial of a hospital's wage data

revision request, CMS pays the hospital by applying a revised wage index that reflects the revised wage data as if CMS's decision had been favorable rather than unfavorable.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.63, see the List of Sections Affected, which appears in the finding Aids section of the printed volume and on GPO Access.

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

(a) *General rule.* CMS determines a national adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge in Federal fiscal year 2005 and subsequent fiscal years involving inpatient hospital services of a hospital in the United States subject to the prospective payment system for which payment may be made under Medicare Part A.

(b) *Geographic classifications.* (1) For purposes of this section, the following definitions apply:

(i) The term *region* means one of the 9 metropolitan divisions comprising the 50 States and the District of Columbia, established by the Executive Office of Management and Budget for statistical and reporting purposes.

(ii) The term *urban area* means—

(A) A Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget; or

(B) The following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Public Law 98–21, 42 U.S.S. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

(C) The term *rural area* means any area outside an urban area.

(D) The phrase *hospital reclassified as rural* means a hospital located in a county that, in FY 2004, was part of an MSA, but was redesignated as rural after September 30, 2004, as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003.

(2) For hospitals within an MSA that crosses census division boundaries, the MSA is deemed to belong to the census division in which most of the hospitals within the MSA are located.

(3) For discharges occurring on or after October 1, 2004, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greater number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs. These EOMB standards are set forth in the notice of final revised standards for classification of MSAs published in the FEDERAL REGISTER on December 27, 2000 (65 FR 82228), announced by EOMB on June 6, 2003, and available from CMS, 7500 Security Boulevard, Baltimore, Maryland 21244.

(4) For purposes of this section, any change in an MSA designation is recognized on October 1 following the effective date of the change. Such a change in MSA designation may occur as a result of redesignation of an MSA by the Executive Office of Management and Budget.

(5) For hospitals that consist of two or more separately located inpatient hospital facilities, the national adjusted prospective payment rate is based on the geographic location of the hospital facility at which the discharge occurred.

(c) *Computing the standardized amount.* CMS computes an average standardized amount that is applicable to all hospitals located in all areas, updated by the applicable percentage increase specified in paragraph (d) of this section.

(d) *Applicable percentage change for fiscal year 2005 and for subsequent fiscal years.*

(1) Subject to the provisions of paragraph (d)(2) of this section, the applicable percentage change for fiscal year

2005 and for subsequent years for updating the standardized amount is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

(2) For fiscal years 2005, 2006, and 2007, the applicable percentage change specified in paragraph (d)(1) of this section is reduced by 0.4 percentage points in the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that does not submit quality data on a quarterly basis to CMS, as specified by CMS. Any reduction of the percentage change will apply only to the fiscal year involved and will not be taken into account in computing the applicable percentage increase for a subsequent fiscal year.

(e) *Maintaining budget neutrality.*

(1) CMS makes an adjustment to the standardized amount to ensure that—

(i) Changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate payments to hospitals are not affected; and

(ii) The annual updates and adjustments to the wage index under paragraph (h) of this section are made in a manner that ensures that aggregate payments to hospitals are not affected.

(2) CMS also makes an adjustment to the rates to ensure that aggregate payments after implementation of reclassifications under subpart L of this part are equal to the aggregate prospective payments that would have been made in the absence of these provisions.

(f) *Adjustment for outlier payments.* CMS reduces the adjusted average standardized amount determined under paragraph (c) through (e) of this section by a proportion equal to the proportion (estimated by CMS) to the total amount of payments based on DRG prospective payment rates that are additional payments for outlier cases under subpart F of this part.

(g) *Computing Federal rates for inpatient operating costs for hospitals located in all areas.* For each discharge classified within a DRG, CMS establishes for the fiscal year a national prospective payment rate for inpatient operating costs based on the standardized amount for the fiscal year and the weighting factor determined under § 412.60(b) for that DRG.

(h) *Adjusting for different area wage levels.* CMS adjusts the proportion of the Federal rate for inpatient operating costs that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the national average level of hospital wages and wage-related costs. The adjustment described in this paragraph (h) also takes into account the earnings and paid hours of employment by occupational category.

(1) The wage index is updated annually.

(2) CMS determines the proportion of the Federal rate that is attributable to wages and labor-related costs from time to time, employing a methodology that is described in the annual regulation updating the system of payment for inpatient hospital operating costs.

(3) For discharges occurring on or after October 1, 2004, CMS employs 62 percent as the proportion of the rate that is adjusted for the relative level of hospital wages and wage-related costs, unless employing that percentage would result in lower payments for the hospital than employing the proportion determined under the methodology described in paragraph (h)(2) of this section.

(4) For discharges on or after October 1, 2004 and before September 30, 2007, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology:

(i) CMS computes the ratio of the lowest-to-highest wage index for each all-urban State;

(ii) CMS computes the average of the ratios of the lowest-to-highest wage indexes of all the all-urban States;

(iii) For each all-urban State, CMS determines the higher of the State's

own lowest-to-highest rate (as determined under paragraph (h)(4)(i) of this section) or the average lowest-to-highest rate (as determined under paragraph (h)(4)(ii) of this section);

(iv) For each State, CMS multiplies the rate determined under paragraph (h)(4)(iii) of this section by the highest wage index value in the State;

(v) The product determined under paragraph (h)(4)(iv) of this section is the minimum wage index value for the State.

(5) An all-urban State is a State with no rural areas, as defined in this section, or a State in which there are no hospitals classified as rural. A State with rural areas and with hospitals reclassified as rural under § 412.103 in not an all-urban State.

(i) *Adjusting the wage index to account for commuting patterns of hospital workers.*

(1) *General criteria.* For discharges occurring on or after October 1, 2004, CMS adjusts the hospital wage index for hospitals located in qualifying counties to recognize the commuting patterns of hospital employees. A qualifying county is a county that meets all of the following criteria:

(i) Hospital employees in the county commute to work in an MSA (or MSAs) with a wage index (or wage indices) higher than the wage index of the MSA or rural statewide area in which the county is located.

(ii) At least 10 percent of the county's hospital employees commute to an MSA (or MSAs) with a higher wage index (or wage indices).

(iii) The 3-year average hourly wage of the hospital(s) in the county equals or exceeds the 3-year average hourly wage of all hospitals in the MSA or rural statewide area in which the county is located.

(2) *Amount of adjustment.* A hospital located in a county that meets the criteria under paragraphs (i)(1)(i) through (i)(1)(iii) of this section will receive an increase in its wage index that is equal to a weighted average of the difference between the prereclassified wage index of the MSA (or MSAs) with the higher wage index (or wage indices) and the prereclasssified wage index of the MSA or rural statewide area in which the qualifying county is located, weighted by the overall percentage of the hospital employees residing in the qualifying county who are employed in any MSA with a higher wage index.

(3) *Process for determining the adjustment.*

(i) CMS will use the most accurate data available, as determined by CMS, to determine the out-migration percentage for each county.

(ii) CMS will include, in its annual proposed and final notices of updates to the hospital inpatient prospective payment system, a listing of qualifying counties and the hospitals that are eligible to receive the adjustment to their wage indexes for commuting hospital employees, and the wage index increase applicable to each qualifying county.

(iii) Any wage index adjustment made under this paragraph (i) is effective for a period of 3 fiscal years, except that hospitals in a qualifying county may elect to waive the application of the wage index adjustment. A hospital may waive the application of the wage index adjustment by notifying CMS in writing within 45 days after the publication of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system.

(iv) A hospital in a qualifying county that receives a wage index adjustment under this paragraph (i) is not eligible for reclassification under subpart L of this part or section 1886(d)(8) of the Act.

(j) *Wage index assignment for rural referral centers for FY 2005.*

(1) CMS makes an exception to the wage index assignment of a rural referral center for FY 2005 if the rural referral center meets the following conditions:

(i) The rural referral center was reclassified for FY 2004 by the MGCRB to another MSA, but, upon applying to the MGCRB for FY 2005, was found to be ineligible for reclassification because its average hourly wage was less than 84 percent (but greater than 82 percent) of the average hourly wage of the hospitals geographically located in the MSA to which the rural referral center applied for reclassification for FY 2005.

(ii) The hospital may not qualify for any geographic reclassification under

subpart L of this part, effective for discharges occurring on or after October 1, 2004.

(2) CMS will assign a rural referral center that meets the conditions of paragraph (j)(1) of this section the wage index value of the MSA to which it was reclassified by the MGCRB in FY 2004. The wage index assignment is applicable for discharges occurring during the 3-year period beginning October 1, 2004 and ending September 30, 2007.

(k) *Midyear corrections to the wage index.*

(1) CMS makes a midyear correction to the wage index for an area only if a hospital can show that—

(i) The intermediary or CMS made an error in tabulating its data; and

(ii) The hospital could not have known about the error, or did not have the opportunity to correct the error, before the beginning of the Federal fiscal year.

(2)(i) Except as provided in paragraph (k)(2)(ii) of this section, a midyear correction to the wage index is effective prospectively from the date the change is made to the wage index.

(ii) Effective October 1, 2005, a change to the wage index may be made retroactively to the beginning of the Federal fiscal year, if, for the fiscal year in question, CMS determines all of the following—

(A) The fiscal intermediary or CMS made an error in tabulating data used for the wage index calculation;

(B) The hospital knew about the error in its wage data and requested the fiscal intermediary and CMS to correct the error both within the established schedule for requesting corrections to the wage data (which is at least before the beginning of the fiscal year for the applicable update to the hospital inpatient prospective payment system) and using the established process; and

(C) CMS agreed before October 1 that the fiscal intermediary or CMS made an error in tabulating the hospital's wage data and the wage index should be corrected.

(l) *Judicial decision.* If a judicial decision reverses a CMS denial of a hospital's wage data revision request, CMS pays the hospital by applying a revised wage index that reflects the revised wage data as if CMS's decision had been favorable rather than unfavorable.

[69 FR 49242, Aug. 11, 2004, as amended at 70 FR 47485, Aug. 12, 2005]

Subpart E—Determination of Transition Period Payment Rates for the Prospective Payment System for Inpatient Operating Costs

§ 412.70 General description.

For discharges occurring on or after April 1, 1988, and before October 1, 1996, payments to a hospital are based on the greater of the national average standardized amount or the sum of 85 percent of the national average standardized amount and 15 percent of the average standardized amount for the region in which the hospital is located.

[57 FR 39822, Sept. 1, 1992, as amended at 58 FR 46338, Sept. 1, 1993]

§ 412.71 Determination of base-year inpatient operating costs.

(a) *Base-year costs.* (1) For each hospital, the intermediary will estimate the hospital's Medicare Part A allowable inpatient operating costs, as described in § 412.2(c), for the 12-month or longer cost reporting period ending on or after September 30, 1982 and before September 30, 1983.

(2) If the hospital's last cost reporting period ending before September 30, 1983 is for less than 12 months, the base period will be the hospital's most recent 12-month or longer cost reporting period ending before such short reporting period, with an appropriate adjustment for inflation. (The rules applicable to new hospitals are set forth in § 412.74.)

(b) *Modifications to base-year costs.* Prior to determining the hospital-specific rate, the intermediary will adjust the hospital's estimated base-year inpatient operating costs, as necessary, to include malpractice insurance costs in accordance with § 413.53(a)(1)(i) of this chapter, and exclude the following:

(1) Medical education costs as described in § 413.85 of this chapter.

(2) Capital-related costs as described in § 413.130 of this chapter.

(3) Kidney acquisition costs incurred by hospitals approved as renal transplantation centers as described in § 412.100. Kidney acquisition costs in the base year will be determined by multiplying the hospital's average kidney acquisition cost per kidney times the number of kidney transplants covered by Medicare Part A during the base period.

(4) Higher costs that were incurred for purposes of increasing base-year costs.

(5) One-time nonrecurring higher costs or revenue offsets that have the effect of distorting base-year costs as an appropriate basis for computing the hospital-specific rate.

(6) Higher costs that result from changes in hospital accounting principles initiated in the base year.

(7) The costs of qualified nonphysician anesthetists' services, as described in § 412.113(c).

(c) *Hospital's request for adjustment of base-year inpatient operating costs.* (1) Before the date it becomes subject to the prospective payment system for inpatient operating costs, a hospital may request the intermediary to further adjust its estimated base-period costs to take into account the following:

(i) Services paid for under Medicare Part B during the hospital's base year that will be paid for under prospective payments. The base-year costs may be increased to include estimated payments for certain services previously billed as physicians' services before the effective date of § 415.102(a) of this chapter, and estimated payments for nonphysicians' services that were not furnished either directly or under arrangements before October 1, 1983 (the effective date of § 405.310(m) of this chapter), but may not include the costs of anesthetists' services for which a physician employer continues to bill under § 405.553(b)(4) of this chapter.

(ii) The payment of FICA taxes during cost reporting periods subject to the prospective payment system, if the hospital had not paid such taxes for all its employees during its base period and will be required to participate effective January 1, 1984.

(2) If a hospital requests that its base-period costs be adjusted under paragraph (c)(1) of this section, it must timely provide the intermediary with sufficient documentation to justify the adjustment, and adequate data to compute the adjusted costs. The intermediary decides whether to use part or all of the data on the basis of audit, survey and other information available.

(d) *Intermediary's determination.* The intermediary uses the best data available at the time in estimating each hospital's base-year costs and the modifications to those costs authorized by paragraphs (b) and (c) of this section. The intermediary's estimate of base-year costs and modifications thereto is final and may not be changed after the first day of the first cost reporting period beginning on or after October 1, 1983, except as provided in § 412.72.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 52 FR 33057, Sept. 1, 1987; 57 FR 33897, July 31, 1992; 57 FR 39822, Sept. 1, 1992; 59 FR 45398, Sept. 1, 1994; 60 FR 63188, Dec. 8, 1995]

§ 412.72 Modification of base-year costs.

(a) *Bases for modification of base-year costs.* Base-year costs as determined under § 412.71(d) may be modified under the following circumstances:

(1) *Inadvertent omissions.* (i) A hospital that becomes subject to the prospective payment system beginning on or after October 1, 1983 and before November 16, 1983 has until November 15, 1983 to request its intermediary to reestimate its base-period costs to take into account inadvertent omissions in its previous submissions to the intermediary related to changes made by the prospective payment legislation for purposes of estimating the base-period costs.

(ii) The intermediary may also initiate changes to the estimation—

(A) For any reason before the date the hospital becomes subject to prospective payment; and

(B) Before November 16, 1983, for corrections to take into account inadvertent omissions in the hospital's previous submissions related to changes made by the prospective payment legislation for purposes of estimating the base-period costs.

(iii) Such omissions pertain to adjustments to exclude capital-related costs and the direct medical education costs of approved educational activities and to adjustments specified in § 412.71(c).

(iv) The intermediary must notify the provider of any change to the hospital-specific amount as a result of the provider's request within 30 days of receipt of the additional data.

(v) Any change to base-period costs made under this paragraph (a)(1) will be made effective retroactively, beginning with the first day of the affected hospital's fiscal year.

(2) *Correction of mathematical errors of calculations.* (i) The hospital must report mathematical errors of calculations to the intermediary within 90 days of the intermediary's notification to the hospital of the hospital's payments rates.

(ii) The intermediary may also identify such errors and initiate their correction during this period.

(iii) The intermediary will either make an appropriate adjustment or notify the hospital that no adjustment is warranted within 30 days of receipt of the hospital's report of an error.

(iv) Corrections of errors of calculation will be effective with the first day of the hospital's first cost reporting period subject to the prospective payment system.

(3) *Recognition of additional costs.* (i) The intermediary may adjust base-period costs to take into account additional costs recognized as allowable costs for the hospital's base year as the result of any of the following:

(A) A reopening and revision of the hospital's base-year notice of amount of program reimbursement under §§ 405.1885 through 405.1889 of this chapter.

(B) A prehearing order or finding issued during the provider payment appeals process by the appropriate reviewing authority under § 405.1821 or § 405.1853 of this chapter that resolved a matter at issue in the hospital's base-year notice of amount of program reimbursement.

(C) An affirmation, modification, or reversal of a Provider Reimbursement Review Board decision by the Administrator of CMS under § 405.1875 of this chapter that resolved a matter at issue in the hospital's base-year notice of amount of program reimbursement.

(D) An administrative or judicial review decision under §§ 405.1831, 405.1871, or 405.1877 of this chapter that is final and no longer subject to review under applicable law or regulations by a higher reviewing authority, and that resolved a matter at issue in the hospital's base-year notice of amount of program reimbursement.

(ii) The intermediary will recalculate the hospital's base-year costs, incorporating the additional costs recognized as allowable for the hospital's base year. Adjustments to base-year costs to take into account these additional costs—

(A) Will be effective with the first day of the hospital's first cost reporting period beginning on or after the date of the revision, order or finding, or review decision; and

(B) Will not be used to recalculate the hospital-specific portion as determined for fiscal years beginning before the date of the revision, order or finding, or review decision.

(4) *Successful appeal.* The intermediary may modify base-year costs to take into account a successful appeal relating to modifications to base-year costs that were made under § 412.71(b). If a hospital successfully contests a modification to base-year costs—

(i) The intermediary will recalculate the hospital's base-year costs to reflect the modification determined appropriate as a result of the appeal; and

(ii) Such adjustments will be effective retroactively to the time of the intermediary's initial estimation of base-year costs.

(5) *Unlawfully claimed costs.* The intermediary may modify base-year costs to exclude costs that were unlawfully claimed as determined as a result of criminal conviction, imposition of a civil judgment under the False Claims Act (31 U.S.C. 3729–3731), or a proceeding for exclusion from the Medicare program. In addition to adjusting base-year costs, CMS will recover both the excess costs reimbursed for the base period and the additional amounts paid due to the inappropriate increase of the hospital-specific portion of the hospital's transition payment rates.

The amount to be recovered will be computed on the basis of the final resolution of the amount of the inappropriate base-year costs.

(b) *Right to administrative and judicial review*. (1) An intermediary's estimation of a hospital's base-year costs, and modifications, made for purposes of determining the hospital-specific rate, are subject to administrative and judicial review. Review will be available to a hospital upon receipt of its notice of amount of program reimbursement following the close of its cost reporting period, but only with respect to whether the intermediary followed the provisions of §§ 412.71 and 412.72. (Sections 405.1803 and 405.1807 of this chapter set forth the rules for intermediary determinations and notice of amount of program reimbursement and the effect of those determinations.)

(2) In any administrative or judicial review of whether the intermediary used the best data available at the time, as required by § 412.71(d), an intermediary's estimation will be revised on the basis of this review only if the estimation was unreasonable and clearly erroneous in light of the data available at the time the estimation was made.

(3) Specifically excluded from administrative or judicial review are any issues based on data, information, or arguments not presented to the intermediary at the time of the estimation.

§ 412.73 Determination of the hospital-specific rate based on a Federal fiscal year 1982 base period.

(a) *Costs on a per discharge basis*. The intermediary will determine the hospital's estimated adjusted base-year operating cost per discharge by dividing the total adjusted operating costs by the number of discharges in the base period.

(b) *Case-mix adjustment*. The intermediary will divide the adjusted base-year costs by the hospital's 1981 case-mix index. If the hospital's case-mix index is statistically unreliable (as determined by CMS), the hospital's base-year costs will be divided by the lower of the following:

(1) The hospital's estimated case-mix index.

(2) The average case-mix index for the appropriate classifications of all hospitals subject to cost limits established under § 413.30 of this chapter for cost reporting periods beginning on or after October 1, 1982 and before October 1, 1983.

(c) *Updating base-year costs*—(1) *For Federal fiscal year 1984*. The case-mix adjusted base-year cost per discharge will be updated by the applicable updating factor, that is, the rate-of-increase percentage determined under § 413.40(c)(3) of this chapter, as adjusted for budget neutrality.

(2) *For Federal fiscal year 1985*. The amount determined under paragraph (c)(1) of this section will be updated by the applicable updating factor, as adjusted for budget neutrality.

(3) *For Federal fiscal year 1986*. (i) The amount determined under paragraph (c)(2) of this section is updated by—

(A) Zero percent for the first seven months of the hospital's cost reporting period; and

(B) One-half of one percent for the remaining five months of the hospital's cost reporting period.

(ii) For purposes of determining the updated base-year costs for cost reporting periods beginning in Federal fiscal year 1987 (that is, on or after October 1, 1986 and before October 1, 1987), the update factor for the previous cost reporting period is deemed to have been one-half of one percent.

(4) *For Federal fiscal year 1987*. The amount determined under paragraph (c)(3)(ii) of this section is updated by 1.15 percent.

(5) *For Federal fiscal year 1988*. (i) For purposes of determining the prospective payment rates for sole community hospitals under § 412.92(d) for cost reporting periods beginning in Federal fiscal year 1988 (that is, on or after October 1, 1987 and before October 1, 1988), the base-year cost per discharge is updated as follows:

(A) For the first 51 days of the hospital's cost reporting period, by zero percent.

(B) For the next 132 days of the hospital's cost reporting period, by 2.7 percent.

(C) For the remainder of the hospital's cost reporting period, by—

(*1*) 3.0 percent for hospitals located in rural areas;

(*2*) 1.5 percent for hospitals located in large urban areas; and

(*3*) 1.0 percent for hospitals located in other urban areas.

(ii) For purposes of determining the updated base-year costs for cost reporting periods beginning in Federal fiscal year 1989 (that is, beginning on or after October 1, 1988 and before October 1, 1989), the update factor for the cost reporting period beginning during federal Fiscal year 1988 is deemed to have been—

(A) 3.0 percent for hospitals located in rural areas;

(B) 1.5 percent for hospitals located in large urban areas; and

(C) 1.0 percent for hospitals located in other urban areas.

(6) *For Federal fiscal year 1989.* For cost reporting periods beginning in Federal fiscal year 1989, the update factor is determined using the methodology set forth in § 412.63(g).

(7) *For Federal fiscal year 1990.* (i) Except as described in paragraph (c)(7)(ii) of this section, for cost reporting periods beginning in Federal fiscal year 1990, the base-period cost per discharge is updated as follows:

(A) For cost reporting periods beginning on or after October 1, 1989 and before January 1, 1990, by 5.5 percent for discharges occurring before January 1, 1990 and by the factors set forth in paragraph (c)(7)(i)(B) of this section for discharges occurring on or after January 1, 1990.

(B) For cost reporting periods beginning on or after January 1, 1990 and before October 1, 1990, by—

(*1*) 9.72 percent for hospitals located in rural areas;

(*2*) 5.62 percent for hospitals located in large urban areas; and

(*3*) 4.97 percent for hospitals located in other urban areas.

(ii) For discharges occurring on or after October 21, 1990 and before January 1, 1991, the base-period cost per discharge, updated as set forth in paragraph (c)(7)(i) of this section, is reduced by 5.5 percent.

(iii) For purposes of determining the updated base-period costs for cost reporting periods beginning in Federal fiscal year 1991 (that is, beginning on or after October 1, 1990 and before October 1, 1991), the update factor for the cost reporting period beginning during Federal fiscal year 1990 is deemed to have been the percentage change provided for in paragraph (c)(7)(i)(B) of this section.

(8) *For Federal fiscal year 1991.* (i) Except as described in paragraph (c)(8)(ii) of this section, for cost reporting periods beginning in Federal fiscal year 1991, the base-period cost per discharge is updated by 5.2 percent.

(ii) For discharges occurring on or after October 21, 1990 and before January 1, 1991, the base-period cost per discharge is updated by 0.0 percent.

(iii) For purposes of determining the updated base period costs for cost reporting periods beginning in Federal fiscal year 1992, the update factor for the cost reporting period beginning during Federal fiscal year 1991 is deemed to have been the percentage change provided for in paragraph (c)(8)(i) of this section.

(9) *For Federal fiscal years 1992 and 1993.* For Federal fiscal years 1992 and 1993, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter).

(10) *For Federal fiscal year 1994.* For Federal fiscal year 1994, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of the chapter) minus 2.3 percentage points. For purposes of determining the hospital-specific rate for Federal fiscal year 1994 and subsequent years, this update factor is adjusted to take into account the portion of the 12-month cost reporting period beginning during Federal fiscal year 1993 that occurs in Federal fiscal year 1994.

(11) *For Federal fiscal year 1995.* For Federal fiscal year 1995, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) minus 2.2 percentage points.

(12) *For Federal fiscal years 1996 through 2000.* For Federal fiscal years 1996 through 2000, the update factor is the applicable percentage change for other prospective payment hospitals in

each respective year as set forth in §§ 412.63(n) through (r).

(13) *For Federal fiscal year 2001.* For Federal fiscal year 2001, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter).

(14) *For Federal fiscal year 2002.* For Federal fiscal year 2002, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) minus 1.1 percentage points.

(15) *For Federal fiscal year 2003 and for subsequent years.* For Federal fiscal year 2003 and subsequent years, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter).

(d) *Budget neutrality*—(1) *Federal fiscal year 1984.* For cost reporting periods beginning on or after October 1, 1983 and before October 1, 1984, CMS adjusts the target rate percentage used under paragraph (c)(1) of this section. This adjustment is based on a factor actuarially estimated to ensure that the estimated amount of aggregate Medicare payments based on the hospital-specific portion of the transition payment rates is neither greater nor less than 75 percent of the amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1984 under the law in effect before April 20, 1983.

(2) *Federal fiscal year 1985.* For cost reporting periods beginning on or after October 1, 1984 and before October 1, 1985, CMS adjusts the target rate percentage used under paragraph (c)(2) of this section. This adjustment is based on a factor actuarially estimated to ensure that the estimated amount of aggregate Medicare payment based on the hospital-specific portion of the transition payment rates is neither greater nor less than 50 percent of the amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1985 under the Social Security Act as in effect on April 19, 1983.

(e) *DRG adjustment.* The applicable hospital-specific cost per discharge is multiplied by the appropriate DRG weighting factor to determine the hospital-specific base payment amount (target amount) for a particular covered discharge.

(f) *Maintaining budget neutrality.* CMS makes an adjustment to the hospital-specific rate to ensure that changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate payments to section 1886(d) hospitals are not affected.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 16787, May 6, 1986; 51 FR 34793, Sept. 30, 1986; 51 FR 42234, Nov. 24, 1986; 52 FR 33057, Sept. 1, 1987; 53 FR 38528, Sept. 30, 1988; 55 FR 15173, Apr. 20, 1990; 56 FR 573, Jan. 7, 1991; 57 FR 39822, Sept. 1, 1992; 58 FR 46338, Sept. 1, 1993; 59 FR 1658, Jan. 12, 1994; 59 FR 32383, June 23, 1994; 65 FR 47106, Aug. 1, 2000; 70 FR 47485, Aug. 12, 2005]

§ 412.75 Determination of the hospital-specific rate for inpatient operating costs based on a Federal fiscal year 1987 base period.

(a) *Base-period costs*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, for each hospital, the intermediary determines the hospital's Medicare part A allowable inpatient operating costs, as described in § 412.2(c), for the 12-month or longer cost reporting period ending on or after September 30, 1987 and before September 30, 1988.

(2) *Exceptions.* (i) If the hospital's last cost reporting period ending before September 30, 1988 is for less than 12 months, the base period is the hospital's most recent 12-month or longer cost reporting period ending before the short period report.

(ii) If the hospital does not have a cost reporting period ending on or after September 30, 1987 and before September 30, 1988 and does have a cost reporting period beginning on or after October 1, 1986 and before October 1, 1987, that cost reporting period is the base period unless the cost reporting period is for less than 12 months. In that case, the base period is the hospital's most recent 12-month or longer cost reporting period ending before the short cost reporting period.

(b) *Costs on a per discharge basis.* The intermediary determines the hospital's average base-period operating cost per

discharge by dividing the total operating costs by the number of discharges in the base period. For purposes of this section, a transfer as defined in § 412.4(b) is considered to be a discharge.

(c) *Case-mix adjustment*. The intermediary divides the average base-period cost per discharge by the hospital's case-mix index for the base period.

(d) *Updating base-period costs*. For purposes of determining the updated base-period costs for cost reporting periods beginning in Federal fiscal year 1988, the update factor is determined using the methodology set forth in § 412.73 (c)(15).

(e) *DRG adjustment*. The applicable hospital-specific cost per discharge is multiplied by the appropriate DRG weighting factor to determine the hospital-specific base payment amount (target amount) for a particular covered discharge.

(f) *Notice of hospital-specific rate*. The intermediary furnishes the hospital a notice of its hospital-specific rate, which contains a statment of the hospital's Medicare part A allowable inpatient operating costs, number of Medicare discharges, and case-mix index adjustment factor used to determine the hospital's cost per discharge for the Federal fiscal year 1987 base period.

(g) *Right to administrative and judicial review*. An intermediary's determination of the hospital-specific rate for a hospital is subject to administrative and judicial review. Review is available to a hospital upon receipt of the notice of the hospital-specific rate. This notice is treated as a final intermediary determination of the amount of program reimbursement for purposes of subpart R of part 405 of this chapter, governing provider reimbursement determinations and appeals.

(h) *Modification of hospital-specific rate*. (1) The intermediary recalculates the hospital-specific rate to reflect the following:

(i) Any modifications that are determined as a result of administrative or judicial review of the hospital-specific rate determinations; or

(ii) Any additional costs that are recognized as allowable costs for the hospital's base period as a result of administrative or judicial review of the base-period notice of amount of program reimbursement.

(2) With respect to either the hospital-specific rate determination or the amount of program reimbursement determination, the actions taken on administrative or judicial review that provide a basis for recalculations of the hospital-specific rate include the following:

(i) A reopening and revision of the hospital's base-period notice of amount of program reimbursement under §§ 405.1885 through 405.1889 of this chapter.

(ii) A prehearing order or finding issued during the provider payment appeals process by the appropriate reviewing authority under § 405.1821 or § 405.1853 of this chapter that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(iii) An affirmation, modification, or reversal of a Provider Reimbursement Review Board decision by the Administrator of CMS under § 405.1875 of this chapter that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(iv) An administrative or judicial review decision under §§ 405.1831, 405.1871, or 405.1877 of this chapter that is final and no longer subject to review under applicable law or regulations by a higher reviewing authority, and that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(v) A final, nonappealable court judgment relating to the base-period costs.

(3) The adjustments to the hospital-specific rate made under paragraphs (h)(1) and (2) of this section are effective retroactively to the time of the intermediary's initial determination of the rate.

(i) *Maintaining budget neutrality*. CMS makes an adjustment to the hospital-specific rate to ensure that changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate

payments to section 1886(d) hospitals are not affected.

[55 FR 15173, Apr. 20, 1990, as amended at 55 FR 36069, Sept. 4, 1990; 55 FR 39775, Sept. 2, 1990; 56 FR 573, Jan. 7, 1991; 55 FR 46887, Nov. 7, 1990; 57 FR 39822, Sept. 1, 1992; 58 FR 46338, Sept. 1, 1993; 65 FR 47106, Aug. 1, 2000; 70 FR 47485, Aug. 12, 2005]

§ 412.77 Determination of the hospital-specific rate for inpatient operating costs for sole community hospitals based on a Federal fiscal year 1996 base period.

(a) *Applicability*. (1) This section applies to a hospital that has been designated as a sole community hospital, as described in § 412.92. If the 1996 hospital-specific rate exceeds the rate that would otherwise apply, that is, either the Federal rate under § 412.64 (or under § 412.63 for periods prior to FY 2005) or the hospital-specific rates for either FY 1982 under § 412.73 or FY 1987 under § 412.75, this 1996 rate will be used in the payment formula set forth in § 412.92(d)(1).

(2) This section applies only to cost reporting periods beginning on or after October 1, 2000.

(3) The formula for determining the hospital-specific costs for hospitals described under paragraph (a)(1) of this section is set forth in paragraph (f) of this section.

(b) *Based costs for hospitals subject to fiscal year 1996 rebasing*. (1) *General rule*. Except as provided in paragraph (b)(2) of this section, for each hospital eligible under paragraph (a) of this section, the intermediary determines the hospital's Medicare Part A allowable inpatient operating costs, as described in § 412.2(c), for the 12-month or longer cost reporting period ending on or after September 30, 1996 and before September 30, 1997, and computes the hospital-specific rate for purposes of determining prospective payment rates for inpatient operating costs as determined under § 412.92(d).

(2) *Exceptions*. (i) If the hospital's last cost reporting period ending before September 30, 1997 is for less than 12 months, the base period is the hospital's most recent 12-month or longer cost reporting period ending before the short period report.

(ii) If the hospital does not have a cost reporting period ending on or after September 30, 1996 and before September 30, 1997, and does have a cost reporting period beginning on or after October 1, 1995 and before October 1, 1996, that cost reporting period is the base period unless the cost reporting period is for less than 12 months. If that cost reporting period is for less than 12 months, the base period is the hospital's most recent 12-month or longer cost reporting period ending before the short cost reporting period. If a hospital has no cost reporting period beginning in fiscal year 1996, the hospital will not have a hospital-specific rate based on fiscal year 1996.

(c) *Costs on a per discharge basis*. The intermediary determines the hospital's average base-period operating cost per discharge by dividing the total operating costs by the number of discharges in the base period. For purposes of this section, a transfer as defined in § 412.4(b) is considered to be a discharge.

(d) *Case-mix adjustment*. The intermediary divides the average base-period cost per discharge by the hospital's case-mix index for the base period.

(e) *Updating base-period costs*. For purposes of determining the updated base-period costs for cost reporting periods beginning in Federal fiscal year 1996, the update factor is determined using the methodology set forth in § 412.73(c)(12) through (c)(15).

(f) *DRG adjustment*. The applicable hospital-specific cost per discharge is multiplied by the appropriate DRG weighting factor to determine the hospital-specific base payment amount (target amount) for a particular covered discharge.

(g) *Notice of hospital-specific rates*. The intermediary furnishes a hospital eligible for rebasing a notice of the hospital-specific rate as computed in accordance with this section. The notice will contain a statement of the hospital's Medicare Part A allowable inpatient operating costs, the number of Medicare discharges, and the case-mix index adjustment factor used to determine the hospital's cost per discharge for the Federal fiscal year 1996 base period.

(h) *Right to administrative and judicial review.* An intermediary's determination of the hospital-specific rate for a hospital is subject to administrative and judicial review. Review is available to a hospital upon receipt of the notice of the hospital-specific rate. This notice is treated as a final intermediary determination of the amount of program reimbursement for purposes of subpart R of part 405 of this chapter.

(i) *Modification of hospital-specific rate.* (1) The intermediary recalculates the hospital-specific rate to reflect the following:

(i) Any modifications that are determined as a result of administrative or judicial review of the hospital-specific rate determinations; or

(ii) Any additional costs that are recognized as allowable costs for the hospital's base period as a result of administrative or judicial review of the base-period notice of amount of program reimbursement.

(2) With respect to either the hospital-specific rate determination or the amount of program reimbursement determination, the actions taken on administrative or judicial review that provide a basis for the recalculations of the hospital-specific rate include the following:

(i) A reopening and revision of the hospital's base-period notice of amount of program reimbursement under §§ 405.1885 through 405.1889 of this chapter.

(ii) A prehearing order or finding issued during the provider payment appeals process by the appropriate reviewing authority under § 405.1821 or § 405.1853 of this chapter that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(iii) An affirmation, modification, or reversal of a Provider Reimbursement Review Board decision by the Administrator of CMS under § 405.1875 of this chapter that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(iv) An administrative or judicial review decision under § 405.1831, § 405.1871, or § 405.1877 of this chapter that is final and no longer subject to review under applicable law or regulations by a higher reviewing authority, and that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(v) A final, nonappealable court judgment relating to the base-period costs.

(3) The adjustments to the hospital-specific rate made under paragraphs (i)(1) and (i)(2) of this section are effective retroactively to the time of the intermediary's initial determination of the rate.

(j) *Maintaining budget neutrality.* CMS makes an adjustment to the hospital-specific rate to ensure that changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate payments to section 1886(d) hospitals are not affected.

[65 FR 47106, Aug. 1, 2000, as amended at 66 FR 32192, June 13, 2001; 70 FR 47485, Aug. 12, 2005]

§ 412.78 Recovery of excess transition period payment amounts resulting from unlawful claims.

If a hospital's base-year costs, as estimated for purposes of determining the hospital-specific portion, are determined, by criminal conviction or imposition of a civil money penalty or assessment, to include costs that were unlawfully claimed, the hospital's base-period costs are adjusted to remove the effect of the excess costs, and CMS recovers both the excess costs reimbursed for the base period and the additional amounts paid due to the inappropriate increase of the hospital-specific portion of the hospital's transition payment rates.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39822, Sept. 1, 1992. Redesignated at 65 FR 47106, Aug. 1, 2000]

Subpart F—Payment for Outlier Cases and Special Treatment Payment for New Technology

PAYMENT FOR OUTLIER CASES

§ 412.80 Outlier cases: General provisions.

(a) *Basic rule*—(1) *Discharges occurring on or after October 1, 1994 and before October 1, 1997.* For discharges occurring on or after October 1, 1994, and before October 1, 1997, except as provided in

paragraph (b) of this section concerning transferring hospitals, CMS provides for additional payment, beyond standard DRG payments, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if either of the following conditions is met:

(i) The beneficiary's length-of-stay (including days at the SNF level of care if a SNF bed is not available in the area) exceeds the mean length-of-stay for the applicable DRG by the lesser of the following:

(A) A fixed number of days, as specified by CMS; or

(B) A fixed number of standard deviations, as specified by CMS.

(ii) The beneficiary's length-of-stay does not exceed criteria established under paragraph (a)(1)(i) of this section, but the hospital's charges for covered services furnished to the beneficiary, adjusted to operating costs and capital costs by applying cost-to-charge ratios as described in § 412.84(h), exceed the DRG payment for the case plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

(2) *Discharges occurring on or after October 1, 1997 and before October 1, 2001.* For discharges occurring on or after October 1, 1997 and before October 1, 2001, except as provided in paragraph (b) of this section concerning transfers, CMS provides for additional payment, beyond standard DRG payments, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if the hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios, as described in § 412.84(h), exceed the DRG payment for the case, payments for indirect costs of graduate medical education (§ 412.105), and payments for serving disproportionate share of low-income patients (§ 412.106), plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

(3) *Discharges occurring on or after October 1, 2001.* For discharges occurring on or after October 1, 2001, except as provided in paragraph (b) of this section concerning transfers, CMS provides for additional payment, beyond standard DRG payments and beyond additional payments for new medical services or technology specified in §§ 412.87 and 412.88, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if the hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios as described in § 412.84(h), exceed the DRG payment for the case (plus payments for indirect costs of graduate medical education (§ 412.105), payments for serving a disproportionate share of low-income patients (§ 412.106), and additional payments for new medical services or technologies) plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

(b) *Outlier cases in transferring hospitals.* CMS provides cost outlier payments to a transferring hospital for cases paid in accordance with § 412.4(f), if the hospital's charges for covered services furnished to the beneficiary, adjusted to costs by applying cost-to-charge ratios as described in § 412.84(h), exceed the DRG payment for the case plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS, divided by the geometric mean length of stay for the DRG, and multiplied by an applicable factor determined as follows:

(1) For transfer cases paid in accordance with § 412.4(f)(1), the applicable factor is equal to the length of stay plus 1 day.

(2) For transfer cases paid in accordance with § 412.4(f)(2), the applicable factor is equal to 0.5 plus the product of the length of stay plus 1 day multiplied by 0.5.

(c) *Publication and revision of outlier criteria.* CMS will issue threshold criteria for determining outlier payment in the annual notice of the prospective payment rates published in accordance with § 412.8(b).

[62 FR 46028, Aug. 29, 1997, as amended at 63 FR 41003, July 31, 1998; 66 FR 46924, Sept. 7, 2001; 67 FR 50111, Aug. 1, 2002]

§ 412.82 Payment for extended length-of-stay cases (day outliers).

(a) For discharges occurring before October 1, 1997, if the hospital stay reflected by a discharge includes covered days of care beyond the applicable threshold criterion, the intermediary

will make an additional payment, on a per diem basis, to the discharging hospital for those days. A special request or submission by the hospital is not necessary to initiate this payment. However, a hospital may request payment for day outliers before the medical review required in paragraph (b) of this section.

(b) The QIO must review and approve to the extent required by CMS—

(1) The medical necessity and appropriateness of the admission and outlier services in the context of the entire stay;

(2) The validity of the diagnostic and procedural coding; and

(3) The granting of grace days.

(c) Except as provided in § 412.86, the per diem payment made under paragraph (a) of this section is derived by taking a percentage of the average per diem payment for the applicable DRG, as calculated by dividing the Federal prospective payment rate for inpatient operating costs and inpatient capital-related costs determined under subpart D of this part, by the arithmetic mean length of stay for that DRG. CMS issues the applicable percentage of the average per diem payment in the annual publication of the prospective payment rates in accordance with § 412.8(b).

(d) Any days in a covered stay identified as noncovered reduce the number of days reimbursed at the day outlier rate but not to exceed the number of days that occur after the day outlier threshold.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 15326, Apr. 17, 1985; 50 FR 35689, Sept. 3, 1985; 53 FR 38529, Sept. 30, 1988; 57 FR 39822, Sept. 1, 1992; 59 FR 45398, Sept. 1, 1994; 62 FR 46028, Aug. 29, 1997]

§ 412.84 Payment for extraordinarily high-cost cases (cost outliers).

(a) A hospital may request its intermediary to make an additional payment for inpatient hospital services that meet the criteria established in accordance with § 412.80(a).

(b) The hospital must request additional payment—

(1) With initial submission of the bill; or

(2) Within 60 days of receipt of the intermediary's initial determination.

(c) Except as specified in paragraph (e) of this section, an additional payment for a cost outlier case is made prior to medical review.

(d) As described in paragraph (f) of this section, the QIO reviews a sample of cost outlier cases after payment. The charges for any services identified as noncovered through this review are denied and any outlier payment made for these services are recovered, as appropriate, after a determination as to the provider's liability has been made.

(e) If the QIO finds a pattern of inappropriate utilization by a hospital, all cost outlier cases from that hospital are subject to medical review, and this review may be conducted prior to payment until the QIO determines that appropriate corrective actions have been taken.

(f) The QIO reviews the cost outlier cases, using the medical records and itemized charges, to verify the following:

(1) The admission was medically necessary and appropriate.

(2) Services were medically necessary and delivered in the most appropriate setting.

(3) Services were ordered by the physician, actually furnished, and not duplicatively billed.

(4) The diagnostic and procedural codings are correct.

(g) The intermediary bases the operating and capital costs of the discharge on the billed charges for covered inpatient services adjusted by the cost to charge ratios applicable to operating and capital costs, respectively, as described in paragraph (h) of this section.

(h) For discharges occurring before October 1, 2003, the operating and capital cost-to-charge ratios used to adjust covered charges are computed annually by the intermediary for each hospital based on the latest available settled cost report for that hospital and charge data for the same time period as that covered by the cost report. For discharges occurring before August 8, 2003, statewide cost-to-charge ratios are used in those instances in which a hospital's operating or capital cost-to-charge ratios fall outside reasonable parameters. CMS sets forth the reasonable parameters and the statewide

cost-to-charge ratios in each year's annual notice of prospective payment rates published in the FEDERAL REGISTER in accordance with § 412.8(b).

(i)(1) For discharges occurring on or after August 8, 2003, CMS may specify an alternative to the ratios otherwise applicable under paragraphs (h) or (i)(2) of this section. A hospital may also request that its fiscal intermediary use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. Such a request must be approved by the CMS Regional Office.

(2) For discharges occurring on or after October 1, 2003, the operating and capital cost-to-charge ratios applied at the time a claim is processed are based on either the most recent settled cost report or the most recent tentative settled cost report, whichever is from the latest cost reporting period.

(3) For discharges occurring on or after August 8, 2003, the fiscal intermediary may use a statewide average cost-to-charge ratio if it is unable to determine an accurate operating or capital cost-to-charge ratio for a hospital in one of the following circumstances:

(i) New hospitals that have not yet submitted their first Medicare cost report. (For this purpose, a new hospital is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18 of this chapter.)

(ii) Hospitals whose operating or capital cost-to-charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean. This mean is recalculated annually by CMS and published in the annual notice of prospective payment rates issued in accordance with § 412.8(b).

(iii) Other hospitals for whom the fiscal intermediary obtains accurate data with which to calculate either an operating or capital cost-to-charge ratio (or both) are not available.

(4) For discharges occurring on or after August 8, 2003, any reconciliation of outlier payments will be based on operating and capital cost-to-charge ratios calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled.

(j) If any of the services are determined to be noncovered, the charges for these services will be deducted from the requested amount of reimbursement but not to exceed the amount claimed above the cost outlier threshold.

(k) Except as provided in paragraph (l) of this section, the additional amount is derived by first taking 80 percent of the difference between the hospital's adjusted operating cost for the discharge (as determined under paragraph (g) of this section) and the operating threshold criteria established under § 412.80(a)(1)(ii); 80 percent is also taken of the difference between the hospital's adjusted capital cost for the discharge (as determined under paragraph (g) of this section) and the capital threshold criteria established under § 412.80(a)(1)(ii). The resulting capital amount is then multiplied by the applicable Federal portion of the payment as determined in § 412.340(a) or § 412.344(a).

(l) For discharges occurring on or after April 1, 1988, the additional payment amount for the DRGs related to burn cases, which are identified in the most recent annual notice of prospective payment rates published in accordance with § 412.8(b), is computed under the provisions of paragraph (k) of this section except that the payment is made using 90 percent of the difference between the hospital's adjusted cost for the discharge and the threshold criteria.

(m) Effective for discharges occurring on or after August 8, 2003, at the time of any reconciliation under paragraph (h)(3) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment will be based upon a widely available index to be established in advance by the Secretary, and will be applied from the

midpoint of the cost reporting period to the date of reconciliation.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35689, Sept. 3, 1985; 51 FR 31496, Sept. 3, 1986; 53 FR 38529, Sept. 30, 1988; 54 FR 36494, Sept. 1, 1989; 55 FR 15174, Apr. 20, 1990; 56 FR 43448, Aug. 30, 1991; 57 FR 39823, Sept. 1, 1992; 59 FR 45398, Sept. 1, 1994; 62 FR 46028, Aug. 29, 1997; 68 FR 34515, June 9, 2003]

§ 412.86 Payment for extraordinarily high-cost day outliers.

For discharges occurring before October 1, 1997, if a discharge that qualifies for an additional payment under the provisions of § 412.82 has charges adjusted to costs that exceed the cost outlier threshold criteria for an extraordinarily high-cost case as set forth in § 412.80(a)(1)(ii), the additional payment made for the discharge is the greater of—

(a) The applicable per diem payment computed under § 412.82 (c) or (d); or

(b) The payment that would be made under § 412.84 (i) or (j) if the case had not met the day outlier criteria threshold set forth in § 412.80(a)(1)(i).

[53 FR 38529, Sept. 30, 1988, as amended at 62 FR 46028, Aug. 29, 1997]

ADDITIONAL SPECIAL PAYMENT FOR CERTAIN NEW TECHNOLOGY

§ 412.87 Additional payment for new medical services and technologies: General provisions.

(a) *Basis.* Sections 412.87 and 412.88 implement sections 1886(d)(5)(K) and 1886(d)(5)(L) of the Act, which authorize the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the hospital inpatient prospective payment system.

(b) *Eligibility criteria.* For discharges occurring on or after October 1, 2001, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical services and technologies, if the following conditions are met:

(1) A new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. CMS will determine whether a new medical service or technology meets this requirement and announce the results of its determinations in the FEDERAL REGISTER as a part of its annual updates and changes to the hospital inpatient prospective payment system.

(2) A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of this section.

(3) The DRG prospective payment rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate, based on application of a threshold amount to estimated charges incurred with respect to such discharges. To determine whether the payment would be adequate, CMS will determine whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant DRGs if the new medical service or technology occurs in many different DRGs). Standardized charges reflect the actual charges of a case adjusted by the prospective payment system payment factors applicable to an individual hospital, such as the wage index, the indirect medical education adjustment factor, and the disproportionate share adjustment factor.

[66 FR 46924, Sept. 7, 2001, as amended at 68 FR 45469, Aug. 1, 2003; 69 FR 49243, Aug. 11, 2004]

§ 412.88 Additional payment for new medical service or technology.

(a) For discharges involving new medical services or technologies that meet the criteria specified in § 412.87, Medicare payment will be:

(1) One of the following:

(i) The full DRG payment (including adjustments for indirect medical education and disproportionate share but excluding outlier payments);

(ii) The payment determined under § 412.4(f) for transfer cases;

(iii) The payment determined under § 412.92(d) for sole community hospitals; or

(iv) The payment determined under § 412.108(c) for Medicare-dependent hospitals; plus

(2) If the costs of the discharge (determined by applying cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(i) 50 percent of the costs of the new medical service or technology; or

(ii) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

(b) Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus 50 percent of the estimated costs of the new medical service or technology.

[66 FR 46924, Sept. 7, 2001, as amended at 67 FR 50111, Aug. 1, 2002; 69 FR 49244, Aug. 11, 2004]

Subpart G—Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Operating Costs

§ 412.90 General rules.

(a) *Sole community hospitals.* CMS may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other hosptials, is the sole source of inpatient hospital services reasonably available in a geographic area to Medicare beneficiaries. If a hospital meets the criteria for such an exception under § 412.92(a), its prospective payment rates for inpatient operating costs are determined under § 412.92(d).

(b) *Referral center.* CMS may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital acts as a referral center for patients transferred from other hospitals. Criteria for identifying such referral centers are set forth in § 412.96.

(c) [Reserved]

(d) *Kidney acquisition costs incurred by hospitals approved as renal transplantation centers.* CMS pays for kidney acquisition costs incurred by renal transplanation centers on a reasonable cost basis. The criteria for this special payment provision are set forth in § 412.100.

(e) *Hospitals located in areas that are reclassified from urban to rural.* (1) CMS adjusts the rural Federal payment amounts for inpatient operating costs for hospitals located in geographic areas that are reclassified from urban to rural as defined in subpart D of this part. This adjustment is set forth in § 412.102.

(2) CMS establishes a procedure by which certain individual hospitals located in urban areas may apply for reclassification as rural. The criteria for reclassification are set forth in § 412.103.

(f) *Hospitals that have a high percentage of ESRD beneficiary discharges.* CMS makes an additional payment to a hospital if ten percent or more of its total Medicare discharges in a cost reporting period beginning on or after October 1, 1984 are ESRD beneficiary discharges. In determining ESRD discharges, discharges in DRG Nos. 302, 316, and 317 are excluded. The criteria for this additional payment are set forth in § 412.104.

(g) *Hosptials that incur indirect costs for graduate medical education programs.* CMS makes an additional payment for inpatient operating costs to a hospital for indirect medical education costs attributable to an approved graduate medical education program. The criteria for this additional payment are set forth in § 412.105.

(h) *Hospitals that serve a disproportionate share of low-income patients.* For discharges occurring on or after May 1,

1986, CMS makes an additional payment for inpatient operating costs to hospitals that serve a disproportionate share of low-income patients. The criteria for this additional payment are set forth in § 412.106.

(i) *Hospitals that receive an additional update for FYs 1998 and 1999.* For FYs 1998 and 1999, CMS makes an upward adjustment to the standardized amounts for certain hospitals that do not receive indirect medical education or disproportionate share payments and are not Medicare- dependent, small rural hospitals. The criteria for identifying these hospitals are set forth in § 412.107.

(j) *Medicare-dependent, small rural hospitals.* For cost reporting periods beginning on or after April 1, 1990 and before October 1, 1994, or beginning on or after October 1, 1997 and before October 1, 2006, CMS adjusts the prospective payment rates for inpatient operating costs determined under subparts D and E of this part if a hospital is classified as a Medicare-dependent, small rural hospital.

(k) *Essential access community hospitals (EACHs).* If a hospital was designated as an EACH by CMS as described in § 412.109(a) and is located in a rural area as defined in § 412.109(b), CMS determines the prospective payment rate for that hospital, as it does for sole community hospitals, under § 412.92(d).

[57 FR 39823, Sept. 1, 1992, as amended at 58 FR 30669, May 26, 1993; 62 FR 46028, Aug. 29, 1997; 64 FR 67051, Nov. 30, 1999; 65 FR 47047, Aug. 1, 2000; 70 FR 47485, Aug. 12, 2005]

§ 412.92 Special treatment: Sole community hospitals.

(a) *Criteria for classification as a sole community hospital.* CMS classifies a hospital as a sole community hospital if it is located more than 35 miles from other like hospitals, or it is located in a rural area (as defined in § 412.64) and meets one of the following conditions:

(1) The hospital is located between 25 and 35 miles from other like hospitals and meets one of the following criteria:

(i) No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area;

(ii) The hospital has fewer than 50 beds and the intermediary certifies that the hospital would have met the criteria in paragraph (a)(1)(i) of this section were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital; or

(iii) Because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(2) The hospital is located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(3) Because of distance, posted speed limits, and predictable weather conditions, the travel time between the hospital and the nearest like hospital is at least 45 minutes.

(b) *Classification procedures.* (1) *Request for classification as sole community hospital.* (i) The hospital must make its request to its fiscal intermediary.

(ii) If a hospital is seeking sole community hospital classification under paragraph (a)(1)(i) or (a)(1)(ii) of this section, the hospital must include the following information with its request:

(A) The hospital must provide patient origin data (for example, the number of patients from each zip code from which the hospital draws inpatients) for all inpatient discharges to document the boundaries of its service area.

(B) The hospital must provide patient origin data from all other hospitals located within a 35 mile radius of it or, if larger, within its service area, to document that no more than 25 percent of either all of the population or the Medicare beneficiaries residing in the hospital's service area and hospitalized for inpatient care were admitted to other like hospitals for care.

(iii)(A) If the hospital is unable to obtain the information required under

paragraph (b)(1)(ii)(A) of this section concerning the residences of Medicare beneficiaries who were inpatients in other hospitals located within a 35 mile radius of the hospital or, if larger, within the hospital's service area, the hospital may request that CMS provide this information.

(B) If a hospital obtains the information as requested under paragraph (b)(1)(iii)(A) of this section, that information is used by both the intermediary and CMS in making the determination of the residences of Medicare beneficiaries under paragraphs (b)(1)(iii) and (b)(1)(iv) of this section, regardless of any other information concerning the residences of Medicare beneficiaries submitted by the hospital.

(iv) The intermediary reviews the request and send the request, with its recommendation, to CMS.

(v) CMS reviews the request and the intermediary's recommendation and forward its approval or disapproval to the intermediary.

(2) *Effective dates of classification.* (i) Sole community hospital status is effective 30 days after the date of CMS's written notification of approval.

(ii) When a court order or a determination by the Provider Reimbursement Review Board (PRRB) reverses an CMS denial of sole community hospital status and no further appeal is made, the sole community hospital status is effective as follows:

(A) If the hospital's application was submitted prior to October 1, 1983, its status as a sole community hospital is effective at the start of the cost reporting period for which it sought exemption from the cost limits.

(B) If the hospital's application for sole community hospital status was filed on or after October 1, 1983, the effective date is 30 days after the date of CMS's original written notification of denial.

(iii) When a hospital is granted retroactive approval of sole community hospital status by a court order or a PRRB decision and the hospital wishes its sole community hospital status terminated before the date of the court order or PRRB determination, it must submit written notice to the CMS regional office within 90 days of the court order or PRRB decision. A written request received after the 90-day period is effective no later than 30 days after the request is submitted.

(iv) A hospital classified as a sole community hospital receives a payment djustment, as described in paragraph (d) of this section, effective with discharges occurring on or after 30 days after the date of CMS's approval of the classification.

(3) *Duration of classification.* An approved classification as a sole community hospital remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved.

(4) *Cancellation of classification.* (i) A hospital may at any time request cancellation of its classification as a sole community hospital, and be paid at rates determined under subparts D and E of this part, as appropriate.

(ii) The cancellation becomes effective no later than 30 days after the date the hospital submits its request.

(iii) If a hospital requests that its sole community hospital classification be cancelled, it may not be reclassified as a sole community hospital unless it meets the following conditions:

(A) At least one full year has passed since the effective date of its cancellation.

(B) The hospital meets the qualifying criteria set forth in paragraph (a) of this section in effect at the time it reapplies.

(5) *Automatic classification as a sole community hospital.* A hospital that has been granted an exemption from the hospital cost limits before October 1, 1983, or whose request for the exemption was received by the appropriate intermediary before October 1, 1983, and was subsequently approved, is automatically classified as a sole community hospital unless that classification has been cancelled under paragraph (b)(3) of this section, or there is a change in the circumstances under which the classification was approved.

(c) *Terminology.* As used in this section—

(1) The term *miles* means the shortest distance in miles measured over improved roads. An improved road for this purpose is any road that is maintained by a local, State, or Federal

government entity and is available for use by the general public. An improved road includes the paved surface up to the front entrance of the hospital.

(2) The term *like hospital* means a hospital furnishing short-term, acute care. Effective with cost reporting periods beginning on or after October 1, 2002, for purposes of a hospital seeking sole community hospital designation, CMS will not consider the nearby hospital to be a like hospital if the total inpatient days attributable to units of the nearby hospital that provides a level of care characteristic of the level of care payable under the acute care hospital inpatient prospective payment system are less than or equal to 8 percent of the similarly calculated total inpatient days of the hospital seeking sole community hospital designation.

(3) The term *service area* means the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12-month cost reporting period ending before it applies for classification as a sole community hospital.

(d) *Determining prospective payment rates for inpatient operating costs for sole community hospitals.* (1) *General rule.* For cost reporting periods beginning on or after April 1, 1990, a sole community hospital is paid based on whichever of the following amounts yields the greatest aggregate payment for the cost reporting period:

(i) The Federal payment rate applicable to the hospitals as determined under subpart D of this part.

(ii) The hospital-specific rate as determined under § 412.73.

(iii) The hospital-specific rate as determined under § 412.75.

(iv) For cost reporting periods beginning on or after October 1, 2000, the hospital-specific rate as determined under § 412.77 (calculated under the transition schedule set forth in paragraph (d)(2) of this section).

(2) *Transition of FY 1996 hospital-specific rate.* The intermediary calculates the hospital-specific rate determined on the basis of the fiscal year 1996 base period rate as follows:

(i) For Federal fiscal year 2001, the hospital-specific rate is the sum of 75 percent of the greater of the amounts specified in paragraph (d)(1)(i), (d)(1)(ii), or (d)(1)(iii) of this section, plus 25 percent of the hospital-specific rate as determined under § 412.77.

(ii) For Federal fiscal year 2002, the hospital-specific rate is the sum of 50 percent of the greater of the amounts specified in paragraph (d)(1)(i), (d)(1)(ii), or (d)(1)(iii) of this section, plus 50 percent of the hospital-specific rate as determined under § 412.77.

(iii) For Federal fiscal year 2003, the hospital-specific rate is the sum of 25 percent of the greater of the amounts specified in paragraph (d)(1)(i), (d)(1)(ii), or (d)(1)(iii) of this section, plus 75 percent of the hospital-specific rate as determined under § 412.77.

(iv) For Federal fiscal year 2004 and any subsequent fiscal years, the hospital-specific rate is 100 percent of the hospital-specific rate specified in paragraph (d)(1)(iv) of this section.

(3) *Adjustment to payments.* A sole community hospital may receive an adjustment to its payments to take into account a significant decrease in the number of discharges, as described in paragraph (e) of this section.

(e) *Additional payments to sole community hospitals experiencing a significant volume decrease.* (1) For cost reporting periods beginning on or after October 1, 1983, the intermediary provides for a payment adjustment for a sole community hospital for any cost reporting period during which the hospital experiences, due to circumstances as described in paragraph (e)(2) of this section a more than five percent decrease in its total discharges of inpatients as compared to its immediately preceding cost reporting period. If either the cost reporting period in question or the immediately preceding cost reporting period is other than a 12-month cost reporting period, the intermediary must convert the discharges to a monthly figure and multiply this figure by 12 to estimate the total number of discharges for a 12-month cost reporting period.

(2) To qualify for a payment adjustment on the basis of a decrease in discharges, a sole community hospital must submit its request no later than 180 days after the date on the intermediary's Notice of Amount of Program Reimbursement—

(i) Submit to the intermediary documentation demonstrating the size of the decrease in discharges, and the resulting effect on per discharge costs; and

(ii) Show that the decrease is due to circumstances beyond the hospital's control.

(3) The intermediary determines a lump sum adjustment amount not to exceed the difference between the hospital's Medicare inpatient operating costs and the hospital's total DRG revenue for inpatient operating costs based on DRG-adjusted prospective payment rates for inpatient operating costs (including outlier payments for inpatient operating costs determined under subpart F of this part and additional payments made for inpatient operating costs for hospitals that serve a disproportionate share of low-income patients as determined under § 412.106 and for indirect medical education costs as determined under § 412.105).

(i) In determining the adjustment amount, the intermediary considers—

(A) The individual hospital's needs and circumstances, including the reasonable cost of maintaining necessary core staff and services in view of minimum staffing requirements imposed by State agencies;

(B) The hospital's fixed (and semi-fixed) costs, other than those costs paid on a reasonable cost basis under part 413 of this chapter; and

(C) The length of time the hospital has experienced a decrease in utilization.

(ii) The intermediary makes its determination within 180 days from the date it receives the hospital's request and all other necessary information.

(iii) The intermediary determination is subject to review under subpart R of part 405 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 31496, Sept. 3, 1986; 51 FR 34793, Sept. 30, 1986; 52 FR 30367, Aug. 14, 1987; 52 FR 33057, Sept. 1, 1987; 53 FR 38529, Sept. 30, 1988; 54 FR 36494, Sept. 1, 1989; 55 FR 14283, Apr. 17, 1990; 55 FR 15174, Apr. 20, 1990; 55 FR 36070, Sept. 4, 1990; 56 FR 25487, June 4, 1991; 57 FR 39823, Sept. 1, 1992; 60 FR 45848, Sept. 1, 1995; 65 FR 47107, Aug. 1, 2000; 66 FR 32193, June 13, 2001; 66 FR 39933, Aug. 1, 2001; 67 FR 50111, Aug. 1, 2002; 70 FR 47485, Aug. 12, 2005]

§ 412.96 Special treatment: Referral centers.

(a) *Criteria for classification as a referral center: Basic rule.* CMS classifies a hospital as a referral center only if the hospital is a Medicare participating acute care hospital and meets the applicable criteria of paragraph (b) or (c) of this section.

(b) *Criteria for cost reporting periods beginning on or after October 1, 1983.* The hospital meets either of the following criteria:

(1) The hospital is located in a rural area (as defined in subpart D of this part) and has the following number of beds, as determined under the provisions of § 412.105(b) available for use:

(i) Effective for discharges occurring before April 1, 1988, the hospital has 500 or more beds.

(ii) Effective for discharges occurring on or after April 1, 1988, the hospital has 275 or more beds during its most recently completed cost reporting period unless the hospital submits written documentation with its application that its bed count has changed since the close of its most recently completed cost reporting period for one or more of the following reasons:

(A) Merger of two or more hospitals.

(B) Reopening of acute care beds previously closed for renovation.

(C) Transfer to the prospective payment system of acute care beds previously classified as part of an excluded unit.

(D) Expansion of acute care beds available for use and permanently maintained for lodging inpatients, excluding beds in corridors and other temporary beds.

(2) The hospital shows that—(i) At least 50 percent of its Medicare patients are referred from other hospitals or from physicians not on the staff of the hospital; and

(ii) At least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital, and at least 60 percent of all the services that the hospital furnishes to Medicare beneficiaries are furnished to beneficiaries who live more than 25 miles from the hospital.

(c) *Alternative criteria.* For cost reporting periods beginning on or after October 1, 1985, a hospital that does not

meet the criteria of paragraph (b) of this section is classified as a referral center if it is located in a rural area (as defined in subpart D of this part) and meets the criteria specified in paragraphs (c)(1) and (c)(2) of this section and at least one of the three criteria specified in paragraphs (c)(3), (c)(4), and (c)(5) of this section.

(1) *Case-mix index*. CMS sets forth national and regional case-mix index values in each year's annual notice of prospective payment rates published under § 412.8(b). The methodology CMS uses to calculate these criteria is described in paragraph (h) of this section. The case-mix index value to be used for an individual hospital in the determination of whether it meets the case-mix index criteria is that calculated by CMS from the hospital's own billing records for Medicare discharges as processed by the fiscal intermediary and submitted to CMS. The hospital's case-mix index for discharges (not including discharges from units excluded from the prospective payment system under subpart B of this part) during the most recent Federal fiscal year that ended at least one year prior to the beginning of the cost reporting period for which the hospital is seeking referral center status must be at least equal to–

(i) For hospitals applying for rural referral center status for cost reporting periods beginning on or after October 1, 1985 and before October 1, 1986, the national or regional case-mix index value; or

(ii) For hospitals applying for rural referral center status for cost—reporting periods beginning on or after October 1, 1986, the national case-mix index value as established by CMS or the median case-mix index value for urban hospitals located in each region. In calculating the median case-mix index for each region, CMS excludes the case-mix indexes of hospitals receiving indirect medical education payments as provided in § 412.105.

(2) *Number of discharges*. (i) CMS sets forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates published under § 412.8(b). The methodology CMS uses to calculate these criteria is described in paragraph (i) of this section. Except as provided in paragraph (c)(2)(ii) of this section for an osteopathic hospital, for the hospital's most recently completed cost reporting period, its number of discharges (not including discharges from units excluded from the prospective payment system under subpart B of this part or from newborn units) is at least equal to—

(A) For hospitals applying for rural referral center status for cost reporting periods beginning on or after October 1, 1985 and before October 1, 1986, the number of discharges under either the national or regional criterion; or

(B) For hospitals applying for rural referral center status for cost reporting periods beginning on or after October 1, 1986, 5,000 discharges or, if less, the median number of discharges for urban hospitals located in each region.

(ii) For cost reporting periods beginning on or after January 1, 1986, an osteopathic hospital, recognized by the American Osteopathic Healthcare Association (or any successor organization), that is located in a rural area must have at least 3,000 discharges during its most recently completed cost reporting period to meet the number of discharges criterion. The 3,000 discharches benchmark is also used in evaluating an osteopathic hospital for purposes of the triennial review.

(3) *Medical staff*. More than 50 percent of the hospital's active medical staff are specialists who meet one of the following conditions:

(i) Are certified as specialists by one of the Member Boards of the American Board of Medical Specialties or the Advisory Board of Osteopathic Specialists.

(ii) Have completed the current training requirements for admission to the certification examination of one of the Member Boards of the American Board of Medical Specialties or the Advisory Board of Osteopathic Specialists.

(iii) Have successfully completed a residency program in a medical specialty accredited by the Accreditation Council of Graduate Medical Education or the American Osteopathic Association.

(4) *Source of inpatients.* At least 60 percent of all its discharges are for inpatients who reside more than 25 miles from the hospital.

(5) *Volume of referrals.* At least 40 percent of all inpatients treated at the hospital are referred from other hospitals or from physicians not on the hospital's staff.

(d) *Payment to rural referral centers.* Effective for discharges occurring on or after April 1, 1988, and before October 1, 1994, a hospital that is located in a rural area and meets the criteria of paragraphs (b)(1), (b)(2) or (c) of this section is paid prospective payments for inpatient operating costs per discharge based on the applicable other urban payment rates as determined in accordance with § 412.63, as adjusted by the hospital's area wage index.

(e)–(f) [Reserved]

(g) *Hospital cancellation of referral center status.* (1) A hospital may at any time request cancellation of its status as a referral center and be paid prospective payments per discharge based on the applicable rural rate, as determined in accordance with subpart D of this part.

(2) The cancellation becomes effective no later than 30 days after the date the hospital submits its request.

(3) If a hospital requests that its referral center status be canceled, it may not be reclassified as a referral center unless it meets the qualifying criteria set forth in paragraph (a) of this section in effect at the time it reapplies.

(h) *Methodology for calculating case-mix index criteria.* CMS calculates the national and regional case-mix index value criteria as described in paragraphs (h)(1) through (h)(4) of this section.

(1) *Updating process.* CMS updates the national and regional case-mix index standards using the latest available data from hospitals subject to the prospective payment system for the Federal fiscal year.

(2) *Source of data.* In making the calculations described in paragraph (h)(1) of this section, CMS uses all inpatient hospital bills received for discharges subject to prospective payment during the Federal fiscal year being monitored.

(3) *Effective date.* CMS sets forth the national and regional criteria in the annual notice of prospective payment rates published under § 412.8(b). These criteria are used to determine if a hospital qualifies for referral center status for cost reporting periods beginning on or after October 1 of the Federal fiscal year to which the notice applies.

(i) *Methodology for calculating number of discharges criteria.* For purposes of determining compliance with the national or regional number of discharges criterion under paragraph (c)(2) of this section, CMS calculates the criteria as follows:

(1) *Updating process.* CMS updates the national and regional number of discharges using the latest available data for levels of admissions or discharges or both.

(2) *Source of data.* In making the calculations described in paragraph (i)(1) of this section, CMS uses the most recent hospital admissions or discharge data available.

(3) *Annual notice.* CMS sets forth the national and regional criteria in the annual notice of prospective payment rates published under § 412.8(b). These criteria are compared to an applying hospital's number of discharges for its most recently completed cost reporting period in determining if the hospital qualifies for referral center status for cost reporting periods beginning on or after October 1 of the Federal fiscal year to which the notice applies.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.96, see the List of Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 412.98 [Reserved]

§ 412.100 Special treatment: Renal transplantation centers.

(a) *Adjustments for renal transplantation centers.* (1) CMS adjusts the prospective payment rates for inpatient operating costs determined under subparts D and E of this part for hospitals approved as renal transplantation centers (described at §§ 405.2170 and 405.2171 of this chapter) to remove the estimated net expenses associated with kidney acquisition.

(2) Kidney acquisition costs are treated apart from the prospective payment rate for inpatient operating costs, and payment to the hospital is adjusted in each reporting period to reflect an amount necessary to compensate the hospital for reasonable expenses of kidney acquisition.

(b) *Costs of kidney acquisition.* Expenses recognized under this section include costs of acquiring a kidney, from a live donor or a cadaver, irrespective of whether the kidney was obtained by the hospital or through an organ procurement agency. These costs include—

(1) Tissue typing, including tissue typing furnished by independent laboratories;

(2) Donor and recipient evaluation;

(3) Other costs associated with excising kidneys, such as donor general routine and special care services;

(4) Operating room and other inpatient ancillary services applicable to the donor;

(5) Preservation and perfusion costs;

(6) Charges for registration of recipient with a kidney transplant registry;

(7) Surgeons' fees for excising cadaver kidneys;

(8) Transportation;

(9) Costs of kidneys acquired from other providers or kidney procurement organizations;

(10) Hospital costs normally classified as outpatient costs applicable to kidney excisions (services include donor and donee tissue typing, workup, and related services furnished prior to admission);

(11) Costs of services applicable to kidney excisions which are rendered by residents and interns not in approved teaching programs; and

(12) All pre-admission physicians services, such as laboratory, electroencephalography, and surgeon fees for cadaver excisions, applicable to kidney excisions including the costs of physicians services.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39824, Sept. 1, 1992]

§412.101 Special treatment: Inpatient hospital payment adjustment for low-volume hospitals.

(a) *General considerations.*

(1) CMS provides an additional payment to a qualifying hospital for the higher incremental costs associated with a low volume of discharges. The amount of any additional payment for a qualifying hospital is calculated in accordance with paragraph (b) of this section.

(2) In order to qualify for this adjustment, a hospital must have less than 200 discharges during the fiscal year, as reflected in its cost report specified in paragraph (a)(3) of this section, and be located more than 25 road miles from the nearest subsection (d) hospital.

(3) The fiscal intermediary makes the determination of the discharge count for purposes of determining a hospital's qualification for the adjustment based on the hospital's most recent submitted cost report.

(4) In order to qualify for the adjustment, a hospital must provide its fiscal intermediary with sufficient evidence that it meets the distance requirement specified under paragraph (a)(2) of this section. The fiscal intermediary will base its determination of whether the distance requirement is satisfied upon the evidence presented by the hospital and other relevant evidence, such as maps, mapping software, and inquiries to State and local police, transportation officials, or other government officials.

(b) *Determination of the adjustment amount.* The low-volume adjustment for hospitals that qualify under paragraph (a) of this section is 25 percent for each Medicare discharge.

(c) *Eligibility of new hospitals for the adjustment.* A new hospital will be eligible for a low-volume adjustment under this section once it has submitted a cost report for a cost reporting period that indicates that it meets the number of discharge requirements during the fiscal year and has provided its fiscal intermediary with sufficient evidence that it meets the distance requirement, as specified under paragraph (a)(2) of this section.

[69 FR 49244, Aug. 11, 2004]

§ 412.102 Special treatment: Hospitals located in areas that are reclassified from urban to rural as a result of a geographic redesignation.

Effective on or after October 1, 1983, a hospital reclassified as rural, as defined in subpart D of this part, may receive an adjustment to its rural Federal payment amount for operating costs for two successive fiscal years.

(a) *First year adjustment.* The hospital's rural average standardized amount and disproportionate share payments as described in § 412.106 are adjusted on the basis of an additional amount that equals two-thirds of the difference between the urban standardized amount and disproportionate share payments applicable to the hospital before its reclassification and the rural standardized amount and disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

(b) *Second year adjustment.* If a hospital continues to be reclassified as rural, its rural average standardized amount and disproportionate share payments are adjusted on the basis of an additional amount that equals one-third of the difference between the urban standardized amount and disproportionate share payments applicable to the hospital before its reclassification and the rural standardized amounts and disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

[58 FR 46338, Sept. 1, 1993, as amended at 65 FR 47047, Aug. 1, 2000; 69 FR 49244, Aug. 11, 2004]

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) *General criteria.* A prospective payment hospital that is located in an urban area (as defined in subpart D of this part) may be reclassified as a rural hospital if it submits an application in accordance with paragraph (b) of this section and meets any of the following conditions:

(1) The hospital is located in a rural census tract of a Metropolitan Statistical Area (MSA) as determined under the most recent version of the Goldsmith Modification, the Rural-Urban Commuting Area codes, as determined by the Office of Rural Health Policy (ORHP) of the Health Resources and Services Administration, which is available via the ORHP Web site at: *http://www.ruralhealth.hrsa.gov* or from the U.S. Department of Health and Human Services, Health Resources and Services Administration, Office of Rural Health Policy, 5600 Fishers Lane, Room 9A–55, Rockville, MD 20857.

(2) The hospital is located in an area designated by any law or regulation of the State in which it is located as a rural area, or the hospital is designated as a rural hospital by State law or regulation.

(3) The hospital would qualify as a rural referral center as set forth in § 412.96, or as a sole community hospital as set forth in § 412.92, if the hospital were located in a rural area.

(4) For any period after September 30, 2004 and before October 1, 2006, a CAH in a county that, in FY 2004, was not part of a MSA as defined by the Office of Management and Budget, but as of FY 2005 was included as part of an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, may be reclassified as being located in a rural area for purposes of meeting the rural location requirement in § 485.610(b) of this chapter if it meets any of the requirements in paragraphs (a)(1), (a)(2), or (a)(3) of this section.

(b) *Application requirements.* (1) *Written application.* A hospital seeking reclassification under this section must submit a complete application in writing to CMS in accordance with paragraphs (b)(2) and (b)(3) of this section.

(2) *Contents of application.* An application is complete if it contains an explanation of how the hospital meets the condition that constitutes the basis of the request for reclassification set forth in paragraph (a) of this section, including data and documentation necessary to support the request.

(3) *Mailing of application.* An application must be mailed to the CMS Regional Office by the requesting hospital and may not be submitted by facsimile or other electronic means.

(4) *Notification by CMS.* Within 5 business days after receiving the hospital's

application, the CMS Regional Office will send the hospital a letter acknowledging receipt, with a copy to the CMS Central Office.

(5) *Filing date*. The filing date of the application is the date CMS receives the application.

(c) *CMS review*. The CMS Regional Office will review the application and notify the hospital of its approval or disapproval of the request within 60 days of the filing date.

(d) *Effective dates of reclassification*. (1) Except as specified in paragraph (d)(2) of this section, CMS will consider a hospital that satisfies any of the criteria set forth in paragraph (a) of this section as being located in the rural area of the State in which the hospital is located as of that filing date.

(2) If a hospital's complete application is received in CMS by September 1, 2000, and satisfies any of the criteria set forth in paragraph (a) of this section, CMS will consider the filing date to be January 1, 2000.

(e) *Withdrawal of application*. A hospital may withdraw an application at any time prior to the date of CMS's decision as set forth in paragraph (c) of this section.

(f) *Duration of classification*. An approved reclassification under this section remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved.

(g) *Cancellation of classification*. (1) A hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of its current cost reporting period.

(2) The hospital's cancellation of the classification is effective beginning with the hospital's next full cost reporting period following the date of its request for cancellation.

[65 FR 47048, Aug. 1, 2000, as amended at 69 FR 49244, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 70 FR 47486, Aug. 12, 2005]

§412.104 Special treatment: Hospitals with high percentage of ESRD discharges.

(a) *Criteria for classification*. CMS provides an additional payment to a hospital for inpatient services provided to ESRD beneficiaries who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD beneficiary discharges, excluding discharges classified into DRG 302 (Kidney Transplant), DRG 316 (Renal Failure), or DRG 317 (Admit for Renal Dialysis), where the beneficiary received dialysis services during the inpatient stay, constitute 10 percent or more of its total Medicare discharges.

(b) *Additional payment*. A hospital that meets the criteria of paragraph (a) of this section is paid an additional payment for each ESRD beneficiary discharge except those excluded under paragraph (a) of this section.

(1) The payment is based on the estimated weekly cost of dialysis and the average length of stay of ESRD beneficiaries for the hospital.

(2) The estimated weekly cost of dialysis is the average number of dialysis sessions furnished per week during the 12-month period that ended June 30, 1983 multiplied by the average cost of dialysis for the same period.

(3) The average cost of dialysis includes only those costs determined to be directly related to the dialysis service. (These costs include salary, employee health and welfare, drugs, supplies, and laboratory services.)

(4) The average cost of dialysis is reviewed and adjusted, if appropriate, at the time the composite rate reimbursement for outpatient dialysis is reviewed.

(5) The payment to a hospital equals the average length of stay of ESRD beneficiaries in the hospital, expressed as a ratio to one week, times the estimated weekly cost of dialysis multiplied by the number of ESRD beneficiary discharges except for those excluded under paragraph (a) of this section. This payment is made only on the Federal portion of the payment rate.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39824, Sept. 1, 1992; 69 FR 49244, Aug. 11, 2004]

§412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

CMS makes an additional payment to hospitals for indirect medical education costs using the following procedures:

(a) *Basic data.* CMS determines the following for each hospital:

(1) The hospital's ratio of full-time equivalent residents (except as limited under paragraph (f) of this section) to the number of beds (as determined under paragraph (b) of this section).

(i) Except for the special circumstances for Medicare GME affiliated groups and new programs described in paragraphs (f)(1)(vi) and (f)(1)(vii) of this section for cost reporting periods beginning on or after October 1, 1997, and for the special circumstances for closed hospitals or closed programs described in paragraph (f)(1)(ix) of this section for cost reporting periods beginning on or after October 1, 2002, this ratio may not exceed the ratio for the hospital's most recent prior cost reporting period after accounting for the cap on the number of allopathic and osteopathic full-time equivalent residents as described in paragraph (f)(1)(iv) of this section, and adding to the capped numerator any dental and podiatric full-time equivalent residents.

(ii) The exception for new programs described in paragraph (f)(1)(vii) of this section applies to each new program individually for which the full-time equivalent cap may be adjusted based on the period of years equal to the minimum accredited length of each new program.

(iii) The exception for closed hospitals and closed programs described in paragraph (f)(1)(ix) of this section applies only through the end of the first 12-month cost reporting period in which the receiving hospital trains the displaced full-time equivalent residents.

(iv) In the cost reporting period following the last year the receiving hospital's full-time equivalent cap is adjusted for the displaced resident(s), the resident-to-bed ratio cap in paragraph (a)(1) of this section is calculated as if the displaced full-time equivalent residents had not trained at the receiving hospital in the prior year.

(2) The hospital's DRG revenue for inpatient operating costs based on DRG-adjusted prospective payment rates for inpatient operating costs, excluding outlier payments for inpatient operating costs determined under subpart F of this part and additional payments made under the provisions of § 412.106.

(b) *Determination of the number of beds.* For purposes of this section, the number of beds in a hospital is determined by counting the number of available bed days during the cost reporting period and dividing that number by the number of days in the cost reporting period. This count of available bed days excludes bed days associated with—

(1) Beds in a unit or ward that is not occupied to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system at any time during the 3 preceding months (the beds in the unit or ward are to be excluded from the determination of available bed days during the current month);

(2) Beds in a unit or ward that is otherwise occupied (to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system) that could not be made available for inpatient occupancy within 24 hours for 30 consecutive days;

(3) Beds in excluded distinct part hospital units;

(4) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or ancillary labor/delivery services. This exclusion would not apply if a patient treated in an observation bed is ultimately admitted for acute inpatient care, in which case the beds and days would be included in those counts;

(5) Beds or bassinets in the healthy newborn nursery; and

(6) Custodial care beds.

(c) *Measurement for teaching activity.* The factor representing the effect of teaching activity on inpatient operating costs equals .405 for discharges occurring on or after May 1, 1986.

(d) *Determination of education adjustment factor.* Each hospital's education adjustment factor is calculated as follows:

(1) *Step one.* A factor representing the sum of 1.00 plus the hospital's ratio of full-time equivalent residents to beds, as determined under paragraph (a)(1) of this section, is raised to an exponential power equal to the factor set forth in paragraph (c) of this section.

(2) *Step two*. The factor derived from step one is reduced by 1.00.

(3) *Step three*. The factor derived from completing steps one and two is multiplied by ''c'', and where ''c'' is equal to the following:

(i) For discharges occurring on or after October 1, 1988, and before October 1, 1997, 1.89.

(ii) For discharges occurring during fiscal year 1998, 1.72.

(iii) For discharges occurring during fiscal year 1999, 1.6.

(iv) For discharges occurring during fiscal year 2000, 1.47.

(A) Each hospital receives an amount that is equal in the aggregate to the difference between the amount of payments made to the hospital if ''c'' equaled 1.6, rather than 1.47.

(B) The payment of this amount will not affect any other payments, determinations, or budget neutrality adjustments.

(v) For fiscal year 2001—

(A) For discharges occurring on or after October 1, 2000 and before April 1, 2001, 1.54.

(B) For discharges occurring on or after April 1, 2001 and before October 1, 2001, the adjustment factor is determined as if ''c'' equaled 1.66, rather than 1.54. This payment increase will not apply to discharges occurring after fiscal year 2001 and will not be taken into account in calculating the payment amounts applicable for discharges occurring after fiscal year 2001.

(vi) For discharges occurring during fiscal year 2002, 1.6.

(vii) For discharges occurring on or after October 1, 2002 and before April 1, 2004, 1.35.

(viii) For discharges occurring on or after April 1, 2004 and before October 1, 2004, 1.47.

(ix) For discharges occurring during fiscal year 2005, 1.42.

(x) For discharges occurring during fiscal year 2006, 1.37.

(xi) For discharges occurring during fiscal year 2007, 1.32.

(xii) For discharges occurring during fiscal year 2008 and thereafter, 1.35.

(4) For discharges occurring on or after July 1, 2005, with respect to FTE residents added as a result of increases in the FTE resident cap under paragraph (f)(1)(iv)(C) of this section, the factor derived from completing steps one and two is multiplied by 'c', where 'c' is equal to 0.66.

(e)(1) *Determination of payment amount*. Each hospital's indirect medical education payment under the prospective payment system for inpatient operating costs is determined by multiplying the total DRG revenue for inpatient operating costs, as determined under paragraph (a)(2) of this section, by the applicable education adjustment factor derived in paragraph (d) of this section.

(2) For discharges occurring on or after July 1, 2005, a hospital that counts additional residents as a result of an increase in its FTE resident cap under paragraph (f)(1)(iv)(C) of this section will receive indirect medical education payments based on the sum of the following two indirect medical education adjustment factors:

(i) An adjustment factor that is calculated using the schedule of formula multipliers in paragraph (d)(3) of this section and the hospital's FTE resident count, not including residents attributable to an increase in its FTE cap under paragraph (f)(1)(iv)(C) under this section; and

(ii) An adjustment factor that is calculated using the applicable formula multiplier under paragraph (d)(4) of this section, and the additional number of FTE residents that are attributable to the increase in the hospital's FTE resident cap under paragraph (f)(1)(iv)(C) in this section.

(f) *Determining the total number of full-time equivalent residents for cost reporting periods beginning on or after July 1, 1991*. (1) For cost reporting periods beginning on or after July 1, 1991, the count of full-time equivalent residents for the purpose of determining the indirect medical education adjustment is determined as follows:

(i) The resident must be enrolled in an approved teaching program. An approved teaching program is one that meets one of the following requirements:

(A) Is approved by one of the national organizations listed in §415.152 of this chapter.

(B) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(*1*) The Directory of Graduate Medical Education Programs published by the American Medical Association.

(*2*) The Annual Report and Reference Handbook published by the American Board of Medical Specialties.

(C) Is approved by the Accreditation Council for Graduate Medical Education (ACGME) as a fellowship program in geriatric medicine.

(D) Is a program that would be accredited except for the accrediting agency's reliance upon an accreditation standard that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether the standard provides exceptions or exemptions.

(ii) In order to be counted, the resident must be assigned to one of the following areas:

(A) The portion of the hospital subject to the prospective payment system.

(B) The outpatient department of the hospital.

(C) Effective for discharges occurring on or after October 1, 1997, the time spent by a resident in a nonhospital setting in patient care activities under an approved medical residency training program is counted towards the determination of full-time equivalency if the criteria set forth in § 413.78(c) or § 413.78(d) of this subchapter, as applicable, are met.

(iii)(A) Full-time equivalent status is based on the total time necessary to fill a residency slot. No individual may be counted as more than one full-time equivalent. If a resident is assigned to more than one hospital, the resident counts as a partial full-time equivalent based on the proportion of time worked in any areas of the hospital listed in paragraph (f)(1)(ii) of this section to the total time worked by the resident. A hospital cannot claim the time spent by residents training at another hospital. A part-time resident or one working in an area of the hospital other than those listed under paragraph (f)(1)(ii) of this section (such as a freestanding family practice center or an excluded hospital unit) would be counted as a partial full-time equivalent based on the proportion of time assigned to an area of the hospital listed in paragraph (f)(1)(ii) of this section, compared to the total time necessary to fill a full-time residency slot.

(B) The time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable.

(iv)(A) Effective for discharges occurring on or after October 1, 1997, the total number of FTE residents in the fields of allopathic and osteopathic medicine in either a hospital or a nonhospital setting that meets the criteria listed in paragraph (f)(1)(ii) of this section may not exceed the number of such FTE residents in the hospital (or, in the case of a hospital located in a rural area, effective for discharges occurring on or after April 1, 2000, 130 percent of that number) with respect to the hospital's most recent cost reporting period ending on or before December 31, 1996.

(B) Effective for portions of cost reporting periods beginning on or after July 1, 2005, a hospital's otherwise applicable FTE resident cap may be reduced if its reference resident level is less than its otherwise applicable FTE resident cap in a reference cost reporting period, in accordance with the provisions of § 413.79(c)(3) of this subchapter. The reduction is 75 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level.

(C) Effective for portions of cost reporting periods beginning on or after July 1, 2005, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap (up to 25 additional FTEs) if the criteria specified in § 413.79(c)(4) of this subchapter are met.

(D) A rural hospital redesignated as urban after September 30, 2004, as a result of the most recent census data and implementation of the new labor market area definitions announced by OMB on June 6, 2003, may retain the increases to its full-time equivalent resident cap that it received under paragraphs (f)(1)(iv)(A) and (f)(1)(vii) of this

section while it was located in a rural area.

(v) For a hospital's cost reporting periods beginning on or after October 1, 1997, and before October 1, 1998, the total number of full-time equivalent residents for payment purposes is equal to the average of the actual full-time equivalent resident counts (subject to the requirements listed in paragraphs (f)(1)(ii)(C) and (f)(1)(iv) of this section) for that cost reporting period and the preceding cost reporting period. For a hospital's cost reporting periods beginning on or after October 1, 1998, the total number of full-time equivalent residents for payment purposes is equal to the average of the actual full-time equivalent resident count (subject to the requirements set forth in paragraphs (f)(1)(ii)(C) and (f)(1)(iv) of this section) for that cost reporting period and the preceding two cost reporting periods. If a hospital qualified for an adjustment to the limit established under paragraph (f)(1)(iv) of this section for new medical residency programs created under paragraph (f)(1)(vii) of this section, the count of residents participating in new medical residency training programs above the number included in the hospital's FTE count for the cost reporting period ending during calendar year 1996 is added after applying the averaging rules in this paragraph (f)(l)(v) for a period of years. Residents participating in new medical residency training programs are included in the hospital's FTE count before applying the averaging rules after the period of years has expired. For purposes of this paragraph, for each new program started, the period of years equals the minimum accredited length for each new program. The period of years for each new program begins when the first resident begins training in each new program. Subject to the provisions of paragraph (f)(1)(ix) of this section, FTE residents that are displaced by the closure of either another hospital or another hospital's program are added to the FTE count after applying the averaging rules in this paragraph (f)(l)(v) for the receiving hospital for the duration of time that the displaced residents are training at the receiving hospital. Subject to the provisions of paragraph (f)(1)(x) of this section, effective for cost reporting periods beginning on or after April 1, 2000, FTE residents at an urban hospital in a rural track program are included in the urban hospital's rolling average calculation described in this paragraph (f)(1)(v).

(vi) Hospitals that are part of the same Medicare GME affiliated group (as defined in §413.75(b) of this subchapter) may elect to apply the limit at paragraph (f)(1)(iv) of this section on an aggregate basis, as specified in §413.79(f) of this chapter.

(vii) If a hospital establishes a new medical residency training program, as defined in §413.79(l) of this subchapter, the hospital's full-time equivalent cap may be adjusted in accordance with the provisions of §§413.79(e)(1) through (e)(4) of this subchapter.

(viii) A hospital that began construction of its facility prior to August 5, 1997, and sponsored new medical residency training programs on or after January 1, 1995 and on or before August 5, 1997, that either received initial accreditation by the appropriate accrediting body or temporarily trained residents at another hospital(s) until the facility was completed, may receive an adjustment to its full-time equivalent cap in accordance with the provisions of §413.79(g) of this subchapter.

(ix) A hospital may receive a temporary adjustment to its full-time equivalent cap to reflect residents added because of another hospital's closure if the hospital meets the criteria specified in §§413.79(h)(1) and (h)(2) of this subchapter. If a hospital that closes its residency training program agrees to temporarily reduce its FTE cap according to the criteria specified in §§413.79(h)(1) and (h)(3)(ii) of this subchapter, another hospital(s) may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of the residency training program if the criteria specified in §§413.86(h)(1) and (h)(3)(i) of this subchapter are met.

(x) An urban hospital that establishes a new residency program (as defined in §413.79(l) of this subchapter), or has an existing residency program, with a rural track (or an integrated rural track) may include in its FTE count residents in those rural tracks in

accordance with the applicable provisions of § 413.79(k) of this subchapter.

(xi) Effective for discharges occurring in cost reporting periods beginning on or after November 29, 1999, a hospital may receive an adjustment to its FTE cap of up to three additional FTEs to the extent that the additional residents would have been counted as primary care residents for purposes of the hospital's FTE cap but for the fact that the additional residents were on maternity or disability leave or a similar approved leave of absence, in accordance with the provisions of § 413.79(i) of this subchapter.

(xii) For discharges occurring on or after October 1, 1997, a non-Veterans Affairs (VA) hospital may receive a temporary adjustment to its FTE cap to reflect residents who had been previously trained at a VA hospital and were subsequently transferred to the non-VA hospital, if the hospital meets the criteria and other provisions of § 413.79(j) of this subchapter.

(xiii) For a hospital that was paid under Part 413 of this chapter as a hospital excluded from the hospital inpatient prospective payment system and that subsequently becomes subject to the hospital inpatient prospective payment system, the limit on the total number of FTE residents for payment purposes is determined based on the data from the hospital's most recent cost reporting period ending on or before December 31, 1996.

(xiv) In the case of a merger of a hospital that is excluded from the hospital inpatient prospective payment system and an acute care hospital subject to the hospital inpatient prospective payment system, if the surviving hospital is a hospital subject to the hospital inpatient prospective payment system and no hospital unit that is excluded from the hospital inpatient prospective payment system is created as a result of the merger, the surviving hospital's number of FTE residents for payment purposes is equal to the sum of the FTE resident count of the hospital that is subject to the hospital inpatient prospective payment system as determined under paragraph (f)(1)(ii)(B) of this section and the limit on the total number of FTE residents for the excluded hospital as determined under paragraph (f)(1)(xiii) of this section.

(xv) Effective for discharges occurring on or after October 1, 2005, an urban hospital that reclassifies to a rural area under § 412.103 for fewer than 10 continuous years and then subsequently elects to revert back to urban classification will not be allowed to retain the adjustment to its IME FTE resident cap that it received as a result of being reclassified as rural.

(2) To include a resident in the full-time equivalent count for a particular cost reporting period, the hospital must furnish the following information. The information must be certified by an official of the hospital and, if different, an official responsible for administering the residency program.

(i) A listing, by specialty, of all residents assigned to the hospital and providing services to the hospital during the cost reporting period.

(ii) The name and social security number of each resident.

(iii) The dates the resident is assigned to the hospital.

(iv) The dates the resident is assigned to other hospitals or other freestanding providers and any nonprovider setting during the cost reporting period.

(v) The proportion of the total time necessary to fill a residency slot that the resident is assigned to an area of the hospital listed under paragraph (f)(1)(ii) of this section.

(3) Fiscal intermediaries must verify the correct count of residents.

(g) *Indirect medical education payment for managed care enrollees.* For portions of cost reporting periods occurring on or after January 1, 1998, a payment is made to a hospital for indirect medical education costs, as determined under paragraph (e) of this section, for discharges associated with individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 of the Act or with a Medicare+Choice organization under title XVIII, Part C of the Act during the period, according to the applicable payment percentages described in §§ 413.76(c)(1) through (c)(5) of this subchapter.

[50 FR 12741, Mar. 29, 1985. Redesignated at 56 FR 43241, Aug. 30, 1991]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §412.105, see the List of Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

(a) *General considerations.* (1) The factors considered in determining whether a hospital qualifies for a payment adjustment include the number of beds, the number of patient days, and the hospital's location.

(i) The number of beds in a hospital is determined in accordance with §412.105(b).

(ii) For purposes of this section, the number of patient days in a hospital includes only those days attributable to units or wards of the hospital providing acute care services generally payable under the prospective payment system and excludes patient days associated with—

(A) Beds in excluded distinct part hospital units;

(B) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or ancillary labor/delivery services. This exclusion would not apply if a patient treated in an observation bed is ultimately admitted for acute inpatient care, in which case the beds and days would be included in those counts;

(C) Beds in a unit or ward that is not occupied to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system at any time during the 3 preceding months (the beds in the unit or ward are to be excluded from the determination of available bed days during the current month); and

(D) Beds in a unit or ward that is otherwise occupied (to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system) that could not be made available for inpatient occupancy within 24 hours for 30 consecutive days.

(iii) The hospital's location, in an urban or rural area, is determined in accordance with the definitions in §412.62(f) or §412.64.

(2) The payment adjustment is applied to the hospital's DRG revenue for inpatient operating costs based on DRG-adjusted prospective payment rates for inpatient operating costs, excluding outlier payments for inpatient operating costs under subpart F of this part and additional payments made under the provisions of §412.105.

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of patient days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period.

For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

(c) *Criteria for classification.* A hospital is classified as a ''disproportionate share'' hospital under any of the following circumstances:

(1) The hospital's disproportionate patient percentage, as determined under paragraph (b)(5) of this section, is at least equal to one of the following:

(i) 15 percent, if the hospital is located in an urban area, and has 100 or more beds, or is located in a rural area and has 500 or more beds.

(ii) 30 percent for discharges occurring before April 1, 2001, and 15 percent for discharges occurring on or after April 1, 2001, if the hospital is located in a rural area and either has more than 100 beds and fewer than 500 beds or is classified as a sole community hospital under § 412.92.

(iii) 40 percent for discharges before April 1, 2001, and 15 percent for discharges occurring on or after April 1, 2001, if the hospital is located in an urban area and has fewer than 100 beds.

(iv) 45 percent for discharges before April 1, 2001, and 15 percent for discharges occurring on or after April 1, 2001, if the hospital is located in a rural area and has 100 or fewer beds.

(2) The hospital is located in an urban area, has 100 or more beds, and can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to indigent patients.

(d) *Payment adjustment factor.* (1) *Method of adjustment.* Subject to the reduction factor set forth in paragraph (e) of this section, if a hospital serves a disproportionate number of low-income patients, its DRG revenues for inpatient operating costs are increased by an adjustment factor as specified in paragraph (d)(2) of this section.

(2) *Payment adjustment factors.* (i) If the hospital meets the criteria of paragraph (c)(1)(i) of this section, the payment adjustment factor is equal to one of the following:

(A) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is as follows:

(*1*) For discharges occurring on or after April 1, 1990, and before January 1, 1991, 5.62 percent plus 65 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*2*) For discharges occurring on or after January 1, 1991, and before October 1, 1993, 5.62 percent plus 70 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*3*) For discharges occurring on or after October 1, 1993, and before October 1, 1994, 5.88 percent plus 80 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*4*) For discharges occurring on or after October 1, 1994, 5.88 percent plus 82.5 percent of the difference between

20.2 percent and the hospital's disproportionate patient percentage.

(B) If the hospital's disproportionate patient percentage is less than 20.2 percent, the applicable payment adjustment factor is as follows:

(*1*) For discharges occurring on or after April 1, 1990, and before October 1, 1993, 2.5 percent plus 60 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*2*) For discharges occurring on or after October 1, 1993, 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(ii) If the hospital meets the criteria of paragraph (c)(1)(ii) of this section, the payment adjustment factor is equal to one of the following:

(A) If the hospital is classified as a rural referral center—

(*1*) For discharges occurring before April 1, 2001, the payment adjustment factor is 4 percent plus 60 percent of the difference between the hospital's disproportionate patient percentage and 30 percent.

(*2*) For discharges occurring on or after April 1, 2001, and before April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 19.3 percent and less than 30 percent, the applicable payment adjustment factor is 5.25 percent.

(*iii*) If the hospital's disproportionate patient percentage is greater than or equal to 30 percent, the applicable payment adjustment factor is 5.25 percent plus 60 percent of the difference between 30 percent and the hospital's disproportionate patient percentage.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(B) If the hospital is classified as a sole community hospital—

(*1*) For discharges occurring before April 1, 2001, the payment adjustment factor is 10 percent.

(*2*) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent and less than 30 percent, the applicable payment adjustment factor is 5.25 percent.

(*iii*) If the hospital's disproportionate patient percentage is equal to or greater than 30 percent, the applicable payment adjustment factor is 10 percent.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*iii*) The maximum payment adjustment factor is 12 percent.

(C) If the hospital is classified as both a rural referral center and a sole community hospital, the payment adjustment is—

(*1*) For discharges occurring before April 1, 2001, the greater of—

(*i*) 10 percent; or

(*ii*) 4 percent plus 60 percent of the difference between the hospital's disproportionate patient percentage and 30 percent.

(*2*) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the greater of the adjustments determined under paragraphs (d)(2)(ii)(A) or (d)(2)(ii)(B) of this section.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(D) If the hospital is classified as a rural hospital and is not classified as either a sole community hospital or a rural referral center, and has 100 or more beds—

(*1*) For discharges occurring before April 1, 2001, the payment adjustment factor is 4 percent.

(*2*) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between the hospital's disproportionate patient percentage and 15 percent.

(*ii*) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent, the applicable payment adjustment factor is 5.25 percent.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*iii*) The maximum payment adjustment factor is 12 percent.

(iii) If the hospital meets the criteria of paragraph (c)(1)(iii) of this section—

(A) For discharges occurring before April 1, 2001, the payment adjustment factor is 5 percent.

(B) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(*1*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between the hospital's disproportionate patient percentage and 15 percent.

(*2*) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent, the applicable payment adjustment factor is 5.25 percent.

(C) For discharges occurring on or after April 1, 2004, the following applies:

(*1*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*2*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*3*) The maximum payment adjustment factor is 12 percent.

(iv) If the hospital meets the criteria of paragraph (c)(1)(iv) of this section—

(A) For discharges occurring before April 1, 2001, the payment adjustment factor is 4 percent.

(B) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(*1*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between the hospital's disproportionate patient percentage and 15 percent.

(*2*) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent, the applicable payment adjustment factor is 5.25 percent.

(C) For discharges occurring on or after April 1, 2004, the following applies:

(*1*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*2*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*3*) The maximum payment adjustment factor is 12 percent.

(e) *Reduction in payments beginning FY 1998*. The amounts otherwise payable to a hospital under paragraph (d) of this section are reduced by the following:

(1) For FY 1998, 1 percent.

(2) For FY 1999, 2 percent.

(3) For FY 2000, 3 percent.

(4) For FY 2001:

(i) For discharges occurring on or after October 1, 2000 and before April 1, 2001, 3 percent.

(ii) For discharges occurring on or after April 1, 2001 and before October 1, 2001, 1 percent.

(5) For FY 2002, 3 percent.

(6) For FYs 2003 and thereafter, 0 percent.

[54 FR 36494, Sept. 1, 1989, as amended at 55 FR 14283, Apr. 17, 1990; 55 FR 15174, Apr. 20, 1990; 55 FR 32088, Aug. 7, 1990; 56 FR 573, Jan. 7, 1991; 56 FR 9633, Mar. 7, 1991; 57 FR 39824, Sept. 1, 1992; 60 FR 45848, Sept. 1, 1995; 62 FR 46029, Aug. 29, 1997; 63 FR 41004, July 31, 1998; 65 FR 3139, Jan. 20. 2000; 65 FR 47108, Aug. 1, 2000; 66 FR 32193, June 13, 2001; 66 FR 39934, Aug. 1, 2001; 67 FR 50112, Aug. 1, 2002; 68 FR 45470, Aug. 1, 2003; 69 FR 49246, Aug. 11, 2004]

§412.107 Special treatment: Hospitals that receive an additional update for FYs 1998 and 1999.

(a) *Additional payment update*. A hospital that meets the criteria set forth in paragraph (b) of this section receives the following increase to its applicable percentage amount set forth in §412.63 (p) and (q):

(1) For FY 1998, 0.5 percent.

(2) For FY 1999, 0.3 percent.

(b) *Criteria for classification*. A hospital is eligible for the additional payment update set forth in paragraph (a) of this section if it meets all of the following criteria:

(1) *Definition*. The hospital is not a Medicare-dependent, small rural hospital as defined in §412.108(a) and does not receive any additional payment under the following provisions:

(i) The indirect medical education adjustment made under §412.105.

(ii) The disproportionate share adjustment made under §412.106.

(2) *State criteria*. The hospital is located in a State in which the aggregate payment made under §412.112 (a) and (c) for hospitals described in paragraph (b)(1) of this section for their cost reporting periods beginning in FY 1995 is less than the allowable operating costs described in §412.2(c) for those hospitals.

(3) *Hospital criteria*. The aggregate payment made to the hospital under §412.112 (a) and (c) for the hospital's cost reporting period beginning in the fiscal year in which the additional payment update described in paragraph (a) of this section is made is less than the allowable operating cost described in §412.2(c) for that hospital.

[62 FR 46030, Aug. 29, 1997]

§412.108 Special treatment: Medicare-dependent, small rural hospitals.

(a) *Criteria for classification as a Medicare-dependent, small rural hospital*. (1) *General considerations*. For cost reporting periods beginning on or after April 1, 1990 and ending before October 1, 1994, or beginning on or after October 1, 1997 and ending before October 1, 2006, a hospital is classified as a Medicare-dependent, small rural hospital if it is located in a rural area (as defined in subpart D of this part) and meets all of the following conditions:

(i) The hospital has 100 or fewer beds as defined in § 412.105(b) during the cost reporting period.

(ii) The hospital is not also classified as a sole community hospital under § 412.92.

(iii) At least 60 percent of the hospital's inpatient days or discharges were attributable to individuals receiving Medicare Part A benefits during the hospital's cost reporting period or periods as follows, subject to the provisions of paragraph (a)(1)(iv) of this section:

(A) The hospital's cost reporting period ending on or after September 30, 1987 and before September 30, 1988.

(B) If the hospital does not have a cost reporting period that meets the criterion set forth in paragraph (a)(1)(iii)(A) of this section, the hospital's cost reporting period beginning on or after October 1, 1986, and before October 1, 1987.

(C) At least two of the last three most recent audited cost reporting periods for which the Secretary has a settled cost report.

(iv) If the cost reporting period determined under paragraph (a)(1)(iii) of this section is for less than 12 months, the hospital's most recent 12-month or longer cost reporting period before the short period is used.

(2) *Counting days and discharges.* In counting inpatient days and discharges for purposes of meeting the criteria in paragraph (a)(1)(iii) of this section, only days and discharges from acute care inpatient hospital stays are counted (including days and discharges from swing beds when used for acute care inpatient hospital services), but not including days and discharges from units excluded from the prospective payment system under §§ 412.25 through 412.30 or from newborn nursery units. For purposes of this section, a transfer as defined in § 412.4(b) is considered to be a discharge.

(b) *Classification procedures.* (1) The fiscal intermediary determines whether a hospital meets the criteria specified in paragraph (a) of this section.

(2) A hospital must submit a written request along with qualifying documentation to its fiscal intermediary to be considered for MDH status based on the criterion under paragraph (a)(1)(iii)(C) of this section.

(3) The fiscal intermediary will make its determination and notify the hospital within 90 days from the date that it receives the hospital's request and all of the required documentation.

(4) A determination of MDH status made by the fiscal intermediary is effective 30 days after the date the fiscal intermediary provides written notification to the hospital. An approved MDH status determination remains in effect unless there is a change in the circumstances under which the status was approved.

(5) The fiscal intermediary will evaluate on an ongoing basis, whether or not a hospital continues to qualify for MDH status. This evaluation includes an ongoing review to ensure that the hospital continues to meet all of the criteria specified in paragraph (a) of this section.

(6) If the fiscal intermediary determines that a hospital no longer qualifies for MDH status, the change in status will become effective 30 days after the date the fiscal intermediary provides written notification to the hospital.

(7) A hospital may reapply for MDH status following its disqualification only after it has completed another cost reporting period that has been audited and settled. The hospital must reapply for MDH status in writing to its fiscal intermediary and submit the required documentation.

(8) If a hospital disagrees with an intermediary's determination regarding the hospital's initial or ongoing MDH status, the hospital may notify its fiscal intermediary and submit other documentable evidence to support its claim that it meets the MDH qualifying criteria.

(9) The fiscal intermediary's initial and ongoing determination is subject to review under subpart R of Part 405 of this chapter. The time required by the fiscal intermediary to review the request is considered good cause for granting an extension of the time limit for the hospital to apply for that review.

(c) *Payment methodology.* A hospital that meets the criteria in paragraph (a) of this section is paid for its inpatient

operating costs the sum of paragraphs (c)(1) and (c)(2) of this section.

(1) The Federal payment rate applicable to the hospital, as determined under subpart D of this part, subject to the regional floor defined in §412.70(c)(6).

(2) The amount, if any, determined as follows:

(i) For discharges occurring during the first three 12-month cost reporting periods that begin on or after April 1, 1990, 100 percent of the amount that the Federal rate determined under paragraph (c)(1) of this section is exceeded by the higher of the following:

(A) The hospital-specific rate as determined under §412.73.

(B) The hospital-specific rate as determined under §412.75.

(ii) For discharges occurring during any subsequent cost reporting period (or portion thereof) and before October 1, 1994, and for discharges occurring on or after October 1, 1997 and before October 1, 2006, 50 percent of the amount that the Federal rate determined under paragraph (c)(1) of this section is exceeded by the higher of the following:

(A) The hospital-specific rate as determined under §412.73.

(B) The hospital-specific rate as determined under §412.75.

(d) *Additional payments to hospitals experiencing a significant volume decrease.* (1) CMS provides for a payment adjustment for a Medicare-dependent, small rural hospital for any cost reporting period during which the hospital experiences, due to circumstances as described in paragraph (d)(2) of this section, a more than 5 percent decrease in its total inpatient discharges as compared to its immediately preceding cost reporting period. If either the cost reporting period in question or the immediately preceding cost reporting period is other than a 12-month cost reporting period, the intermediary must convert the discharges to a monthly figure and multiply this figure by 12 to estimate the total number of discharges for a 12-month cost reporting period.

(2) To qualify for a payment adjustment on the basis of a decrease in discharges, a Medicare-dependent, small rural hospital must submit its request no later than 180 days after the date on the intermediary's Notice of Amount of Program Reimbursement and it must—

(i) Submit to the intermediary documentation demonstrating the size of the decrease in discharges and the resulting effect on per discharge costs; and

(ii) Show that the decrease is due to circumstances beyond the hospital's control.

(3) The intermediary determines a lump sum adjustment amount not to exceed the difference between the hospital's Medicare inpatient operating costs and the hospital's total DRG revenue for inpatient operating costs based on DRG-adjusted prospective payment rates for inpatient operating costs (including outlier payments for inpatient operating costs determined under subpart F of this part and additional payments made for inpatient operating costs hospitals that serve a disproportionate share of low-income patients as determined under §412.106 and for indirect medical education costs as determined under §412.105).

(i) In determining the adjustment amount, the intermediary considers—

(A) The individual hospital's needs and circumstances, including the reasonable cost of maintaining necessary core staff and services in view of minimum staffing requirements imposed by State agencies;

(B) The hospital's fixed (and semi-fixed) costs, other than those costs paid on a reasonable cost basis under part 413 of this chapter; and

(C) The length of time the hospital has experienced a decrease in utilization.

(ii) The intermediary makes its determination within 180 days from the date it receives the hospital's request and all other necessary information.

(iii) The intermediary determination is subject to review under subpart R of part 405 of this chapter. The time required by the intermediary to review the request is considered good cause for granting an extension of the time limit

for the hospital to apply for that review.

[55 FR 15175, Apr. 20, 1990; 55 FR 32088, Aug. 7, 1990, as amended at 55 FR 36070, Sept. 4, 1990; 57 FR 39824, Sept. 1, 1992; 58 FR 46339, Sept. 1, 1993; 58 FR 67350, Dec. 21, 1993; 59 FR 45400, Sept. 1, 1994; 62 FR 46030, Aug. 29, 1997; 62 FR 52034, Oct. 6, 1997; 65 FR 47048, Aug. 1, 2000; 66 FR 32194, June 13, 2001; 66 FR 39932, Aug. 1, 2001; 67 FR 50112, Aug. 1, 2002; 69 FR 49247, Aug. 11, 2004; 70 FR 47486, Aug. 12, 2005]

§ 412.109 Special treatment: Essential access community hospitals (EACHs).

(a) *General rule.* For payment purposes, CMS treats as a sole community hospital any hospital that is located in a rural area as described in paragraph (b) of this section and that CMS designated as an EACH under section 1820(i)(1) of the Act as in effect on September 30, 1997, for as long as the hospital continues to comply with the terms, conditions, and limitations that were applicable at the time CMS designated the hospital as an EACH. The payment methodology for sole community hospitals is set forth at § 412.92(d).

(b) *Location in a rural area.* For purposes of this section, a hospital is located in a rural area if it—

(1) Is located outside any area that is a Metropolitan Statistical Area as defined by the Office of Management and Budget or that has been recognized as urban under § 412.62;

(2) Is not deemed to be located in an urban area under subpart D of this part.

(3) Is not classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board; or

(4) Is not located in a rural county that has been redesignated to an adjacent urban area under § 412.232.

(c) *Adjustment to the hospital-specific rate for rural EACH's experiencing increased costs.* (1) *General rule.* CMS increases the applicable hospital-specific rate of an EACH that it treats as a sole community hospital if, during a cost reporting period, the hospital experiences an increase in its Medicare inpatient operating costs per discharge that is directly attributable to activities related to its membership in a rural health network.

(2) *Request and documentation.* In order for a hospital to qualify for an increase in its hospital-specific rate, it must meet the following criteria:

(i) The hospital must submit its request to its intermediary no later than 180 days after the date on the intermediary's notice of program reimbursement.

(ii) The request must include documentation specifically identifying the increased costs resulting from the hospital's participation in a rural health network and show that the increased costs during the cost reporting period will result in increased costs in subsequent cost reporting periods that are not already accounted for under the prospective payment system payment.

(iii) The hospital must show that the cost increases are incremental costs that would not have been incurred in the absence of the hospital's membership in a rural health network.

(iv) The hospital must show that the cost increases do not include amounts for start-up and one-time, nonrecurring costs attributable to its membership in a rural health network.

(3) *Intermediary recommendation.* The intermediary forwards the following material to CMS within 60 days of receipt from the hospital:

(i) The hospital's documentation and the intermediary's verification of that documentation.

(ii) The intermediary's analysis and recommendation of the request.

(iii) The hospital's Medicare cost report for the year in which the increase in costs occurred and the prior year.

(4) *CMS determination.* CMS determines, within 120 days of receiving all necessary information from the intermediary, whether an increase in the hospital-specific rate is warranted and, if it is, the amount of the increase. CMS grants an adjustment only if a hospital's Medicare inpatient operating costs per discharge exceed the hospital's hospital-specific rate. The adjusted hospital-specific rate cannot exceed the hospital's Medicare inpatient operating costs per discharge for the cost reporting period.

(d) *Termination of EACH designation.* If CMS determines that a hospital no

longer complies with the terms, conditions, and limitations that were applicable at the time CMS designated the hospital as an EACH, CMS will terminate the EACH designation of the hospital, effective with discharges occurring on or after 30 days after the date of the determination.

(e) *Review of CMS determination.* A determination by CMS that a hospital's EACH designation should be terminated, is subject to review under part 405, subpart R of this chapter, including the time limits for filing requests for hearings as specified in §§405.1811(a) and 405.1841(a)(1) and (b) of this chapter.

[58 FR 30669, May 26, 1993, as amended at 59 FR 45398, Sept. 1, 1994; 60 FR 45848, Sept. 1, 1995; 61 FR 21972, May 13, 1996; 62 FR 46030, Aug. 29, 1997; 70 FR 47486, Aug. 12, 2005]

Subpart H—Payments to Hospitals Under the Prospective Payment Systems

§412.110 Total Medicare payment.

Under the prospective payment systems, Medicare's total payment for inpatient hospital services furnished to a Medicare beneficiary by a hospital will equal the sum of the payments listed in §§412.112 through 412.115, reduced by the amounts specified in §412.120.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39824, Sept. 1, 1992]

§412.112 Payments determined on a per case basis.

A hospital is paid the following amounts on a per case basis:

(a) The appropriate prospective payment rate for inpatient operating costs for each discharge as determined in accordance with subparts D, E, and G of this part.

(b) Effective for cost reporting periods beginning on or after October 1, 1991, the appropriate prospective payment rate for capital-related costs for each discharge as determined in accordance with subpart M of this part.

(c) The appropriate outlier payment amounts determined under subpart F of this part.

(d) Additional payments for new medical services and technologies determined under subpart F of this part.

[56 FR 43448, Aug. 30, 1991, as amended at 57 FR 39824, Sept. 1, 1992; 68 FR 45470, Aug. 1, 2003]

§412.113 Other payments.

(a) *Capital-related costs.* (1) *Payment.* Subject to the reductions described in paragraph (a)(2) of this section, payment for capital-related costs (as described in §413.130 of this chapter) for cost reporting periods beginning before October 1, 1991 is determined on a reasonable cost basis.

(2) *Reduction to capital-related payments.* (i) Except for sole community hospitals as defined in §412.92, the amount of capital-related payments for cost-reporting periods beginning before October 1, 1991 (including a return on equity capital as provided under §413.157 of this chapter) is reduced by—

(A) Three and one-half percent for payments attributable to portions of cost reporting periods occurring during Federal FY 1987;

(B) Seven percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1988 and before January 1, 1988;

(C) Twelve percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) in fiscal year 1988 occurring on or after January 1, 1988;

(D) Fifteen percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1989 and beginning on or after January 1, 1990 and ending on or before September 30, 1991; and

(E) Ten percent for payments attributable to portions of cost-reporting periods occurring on or after October 1, 1991 and before the beginning of the hospital's first cost-reporting period beginning on or after October 1, 1991.

(ii) If a hospital's cost reporting period encompasses more than one Federal fiscal year, the reductions to capital-related payments are determined on a prorated monthly basis.

(3) For cost-reporting periods beginning on or after October 1, 1991, a hospital with a hospital-specific rate

above the Federal capital rate is paid a hold-harmless payment for old capital determined in accordance with subpart M of this part.

(b) *Direct medical education costs.* (1) Payment for the direct medical education costs of interns and residents in approved programs for cost reporting periods beginning prior to July 1, 1985, and for approved education activities of nurses and paramedical health professionals is made as described in § 413.85 of this chapter.

(2) For cost reporting periods beginning on or after July 1, 1985, payment for the direct medical education costs of interns and residents in approved programs is made as described in §§ 413.75 through 413.83 of this subchapter.

(3) Except as provided in § 413.75(c) of this subchapter, for cost reporting periods during the prospective payment transition period, the costs of medical education must be determined in a manner that is consistent with the treatment of these costs for purposes of determining the hospital-specific portion of the payment rate as provided in subpart E of this part.

(c) *Anesthesia services furnished by hospital or CAH employed nonphysician anesthetists or obtained under arrangements.* (1) For cost reporting periods beginning on or after October 1, 1984 through any part of a cost reporting period occurring before January 1, 1989, payment is determined on a reasonable cost basis for anesthesia services provided in the hospital or CAH by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologist's assistants) employed by the hospital or CAH or obtained under arrangements.

(2)(i) For cost reporting periods, or any part of a cost reporting period, beginning on or after January 1, 1989, through any part of a cost reporting period occurring before January 1, 1990, payment is determined on a reasonable cost basis for anesthesia services provided in a hospital or CAH by qualified nonphysician anesthetists employed by the hospital or CAH or obtained under arrangement, if the hospital or CAH demonstrates to its intermediary prior to April 1, 1989 that it meets the following criteria:

(A) The hospital or CAH is located in a rural area as defined in § 412.62(f) and is not deemed to be located in an urban area under the provisions of § 412.64(b)(3).

(B) The hospital or CAH must have employed or contracted with a qualified nonphysician anesthetist, as defined in § 410.66 of this chapter, as of January 1, 1988 to perform anesthesia services in that hospital or CAH. The hospital or CAH may employ or contract with more than one anesthetist; however, the total number of hours of service furnished by the anesthetists may not exceed 2,080 hours per year.

(C) The hospital or CAH must provide data for its entire patient population to demonstrate that, during calendar year 1987, its volume of surgical procedures (inpatient and outpatient) requiring anesthesia services did not exceed 250 procedures. For purposes of this section, a *surgical procedure requiring anesthesia services* means a surgical procedure in which the anesthesia is administered and monitored by a qualified nonphysician anesthetist, a physician other than the primary surgeon, or an intern or resident.

(D) Each qualified nonphysician anesthetist employed by or under contract with the hospital or CAH has agreed in writing not to bill on a reasonable charge basis for his or her patient care to Medicare beneficiaries in that hospital or CAH.

(ii) To maintain its eligibility for reasonable cost payment under paragraph (c)(2)(i) of this section in calendar years after 1989, a qualified hospital or CAH must demonstrate prior to January 1 of each respective year that for the prior year its volume of surgical procedures requiring anesthesia service did not exceed 500 procedures; or, effective October 1, 2002, did not exceed 800 procedures.

(iii) A hospital or CAH that did not qualify for reasonable cost payment for nonphysician anesthetist services furnished in calendar year 1989 can qualify in subsequent years if it meets the criteria in paragraphs (c)(2)(i)(A), (B), and (D) of this section, and demonstrates to its intermediary prior to the start of

the calendar year that it met these criteria. The hospital or CAH must provide data for its entire patient population to demonstrate that, during calendar year 1987 and the year immediately preceding its election of reasonable cost payment, its volume of surgical procedures (inpatient and outpatient) requiring anesthesia services did not exceed 500 procedures, or, effective October 1, 2002, did not exceed 800 procedures.

(iv) For administrative purposes for the calendar years after 1990, the volume of surgical procedures for the immediately preceding year is the sum of the surgical procedures for the nine month period ending September 30, annualized for the twelve month period.

(d) *Organ acquisition*. Payment for organ acquisition costs incurred by hospitals with approved transplantation centers is made on a reasonable cost basis. The term ''Organs'' is defined in §486.302 of this chapter.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §412.113, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§412.115 Additional payments.

(a) *Bad debts*. An additional payment is made to each hospital in accordance with §413.89 of this chapter for bad debts attributable to deductible and coinsurance amounts related to covered services received by beneficiaries.

(b) *Administration of blood clotting factor*. For discharges occurring on or after June 19, 1990, and before October 1, 1994, and for discharges occurring on or after October 1, 1997, an additional payment is made to a hospital for each unit of blood clotting factor furnished to a Medicare inpatient who is a hemophiliac. For discharges occurring on or after October 1, 2005, the additional payment is made based on the average sales price methodology specified in subpart K, part 414 of this chapter and the furnishing fee specified in §410.63 of this subchapter.

(c) *QIO photocopy and mailing costs*. An additional payment is made to a hospital in accordance with §476.78 of this chapter for the costs of photocopying and mailing medical records requested by a QIO.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 55 FR 15175, Apr. 20, 1990; 56 FR 43448, Aug. 30, 1991; 57 FR 39825, Sept. 1, 1992; 57 FR 47787, Oct. 20, 1992; 58 FR 46339, Sept. 1, 1993; 62 FR 46030, Aug. 29, 1997; 68 FR 67960, Dec. 5, 2003; 70 FR 47486, Aug. 12, 2005]

§412.116 Method of payment.

(a) *General rules*. (1) Unless the provisions of paragraphs (b) and (c) of this section apply, hospitals are paid for hospital inpatient operating costs and capital-related costs for each discharge based on the submission of a discharge bill.

(2) Payments for inpatient hospital services furnished by an excluded psychiatric unit of a hospital (or by an excluded rehabilitation unit of a hospital for cost reporting periods beginning before January 1, 2002) are made as described in §§413.64(a), (c), (d), and (e) of this chapter.

(3) For cost reporting periods beginning on or after January 1, 2005, payments for inpatient hospital services furnished by an inpatient psychiatric facility that meets the conditions of §412.404 are made as described in §412.432.

(4) For cost reporting periods beginning on or after January 1, 2002, payments for inpatient hospital services furnished by a rehabilitation hospital or a rehabilitation unit that meets the conditions of §412.604 are made as described in §412.632.

(5) For cost reporting periods beginning on or after October 1, 2002, payments for inpatient hospital services furnished by a long-term care hospital that meets the conditions for payment of §§412.505 through 412.511 are made as described in §412.521.

(b) *Periodic interim payments*—(1) *Criteria for receiving periodic interim payments*. Effective with claims received on or after July 1, 1987, a hospital that meets the criteria in §413.64(h) of this chapter may request in writing to receive periodic interim payments as described in this paragraph. A hospital that is receiving periodic interim payments also receives payment on this basis for inpatient hospital services

furnished by its excluded psychiatric or rehabilitation unit.

(i) *Failure of intermediary to make prompt payment.* Beginning with claims received in April 1987, the hospital's fiscal intermediary does not meet the requirements of section 1816(c)(2) of the Act, which provides for prompt payment of claims under Medicare Part A, for three consecutive calendar months. The hospital may continue to receive periodic interim payments until the intermediary meets the requirements of section 1816 (c)(2) of the Act for three consecutive calendar months. For purposes of this paragraph, a hospital that is receiving periodic interim payments as of June 30, 1987 and meets the requirements of § 413.64(h) of this chapter may continue to receive payment on this basis until the hospital's intermediary meets the requirements of section 1816(c)(2) of the Act for three consecutive calendar months beginning with April 1987.

(ii) *Hospitals that serve a disproportionate share of low-income patients.* The hospital is receiving periodic interim payments as of June 30, 1987 and has a disproportionate share payment adjustment factor of at least 5.1 percent as determined under § 412.106(c) for purposes of establishing the average standardized amounts for discharges occurring on or after October 1, 1986 and before October 1, 1987. The hospital's request must be made by a date prior to July 1, 1987, specified by the intermediary.

(iii) *Small rural hospitals.* The hospital is receiving periodic interim payments as of June 30, 1987, makes its request by a date prior to July 1, 1987, specified by the intermediary, and, on July 1, 1987, the hospital—

(A) Is located in a rural area as defined in § 412.62(f); and

(B) Has 100 or fewer beds available for use.

(2) *Frequency of payment.* The intermediary estimates a hospital's prospective payments as described in paragraph (b)(3) of this section and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. Each payment is made two weeks after the end of a biweekly period of service, as described in § 413.64(h)(5) of this chapter. These payments are subject to final settlement.

(3) *Amount of payment.* (i) The biweekly interim payment amount is based on the total estimated Medicare discharges for the reporting period multiplied by the hospital's estimated average prospective payment amount as described in paragraph (b)(3)(ii) of this paragraph. These interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if a hospital receives interim payments for less than a full reporting period.

(ii) For purposes of determining periodic interim payments under this paragraph, a hospital's estimated average prospective payment amount is computed as follows:

(A) If a hospital has no payment experience under the prospective payment system for operating costs, the intermediary computes the hospital's estimated average prospective payment amount for operating costs by multiplying its payment rates as determined under § 412.70(c), but without adjustment by a DRG weighting factor, by the hospital's case-mix index, and subtracting from this amount estimated deductibles and coinsurance.

(B) Effective for cost-reporting periods beginning on or after October 1, 1991, the intermediary computes a hospital's estimated average prospective payment amount for capital-related costs by multiplying its prospective payment rate as determined under § 412.340 or § 412.344(a), as applicable, and under § 412.308 for cost reporting periods beginning on or after October 1, 2001 but without adjustment by a DRG weighting factor, by the hospital's case-mix index. The intermediary may take into account estimated additional payments per discharge under § 412.348. If the hospital is paid under § 412.344(a)(1), the intermediary includes an estimated payment for old capital costs per discharge.

(C) If a hospital has payment experience under the prospective payment system for operating costs, and, for cost reporting periods beginning on or after October 1, 1991, for inpatient capital-related costs, the intermediary

computes a hospital's estimated average prospective payment amount for operating costs and capital-related costs based on that payment experience, adjusted for projected changes, and subtracts from this amount estimated deductibles and coinsurance.

(4) *Termination of periodic interim payments*—(i) *Request by the hospital*. A hospital receiving periodic interim payments may convert to payments on a per discharge basis at any time.

(ii) *Removal by the intermediary*. An intermediary terminates periodic interim payments if—

(A) A hospital no longer meets the requirements of §413.64(h);

(B) A hospital is receiving payment under the criterion in paragraph (b)(1)(i) of this section and the intemediary meets the prompt payment requirements of section 1816(c)(2) of the Act for three consecutive calendar months; or

(C) A hospital that is receiving payment under the criterion set forth in paragraph (b)(1)(iii) of this section no longer meets the criterion.

(iii) *Limitation on reelection*. If a hospital that is receiving periodic interim payments under the criterion set forth in paragraph (b)(1)(ii) or (b)(1)(iii) of this section is removed from that method of payment at its own request, it may reelect to receive periodic interim payments only under the criterion set forth in paragraph (b)(1)(i) of this section. However, if the hospital is removed from that method of payment by its intermediary because it no longer meets the requirements of §413.64(h) of this chapter, that hospital may subsequently reelect to receive periodic interim payments if it qualifies under the provisions of paragraph (b)(1)(ii) or (b)(1)(iii) of this section, subject to the requirements in §413.64(h) of this chapter.

(c) *Special interim payments for certain costs*. For capital-related costs for cost-reporting periods beginning before October 1, 1991 and the direct costs of medical education, which are not included in prospective payments but are reimbursed as specified in §§413.130 and 413.85 of this chapter, respectively, interim payments are made subject to final cost settlement. Interim payments for capital-related items for cost-reporting periods beginning before October 1, 1991 and the estimated cost of approved medical education programs (applicable to inpatient costs payable under Medicare Part A and for kidney acquisition costs in hospitals approved as renal transplantation centers) are determined by estimating the reimbursable amount for the year based on the previous year's experience and on substantiated information for the current year and divided into 26 equal biweekly payments. Each payment is made two weeks after the end of a biweekly period of services, as described in §413.64(h)(5) of this chapter. The interim payments are reviewed by the intermediary at least twice during the reporting period and adjusted if necessary.

(d) *Special interim payment for unusually long lengths of stay*—(1) *First interim payment*. A hospital that is not receiving periodic interim payments under paragraph (b) of this section may request an interim payment after a Medicare beneficiary has been in the hospital at least 60 days. Payment for the interim bill is determined as if the bill were a final discharge bill and includes any outlier payment determined as of the last day for which services have been billed.

(2) *Additional interim payments*. A hospital may request additional interim payments at intervals of at least 60 days after the date of the first interim bill submitted under paragraph (d)(1) of this section. Payment for these additional interim bills, as well as the final bill, is determined as if the bill were the final bill with appropriate adjustments made to the payment amount to reflect any previous interim payment made under the provisions of this paragraph (d).

(e) *Outlier payment and additional payments for new medical services and technologies*. Payments for outlier cases and additional payments for new medical services and technologies (described in subpart F of this part) are not made on an interim basis. These payments are made based on submitted bills and represent final payment.

(f) *Accelerated payments*—(1) *General rule*. Upon request, an accelerated payment may be made to a hospital that is

not receiving periodic interim payments under paragraph (b) of this section if the hospital is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the hospital.

(ii) Due to an exceptional situation, there is a temporary delay in the hospital's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* A hospital's request for an accelerated payment must be approved by the intermediary and CMS.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as hospital bills are processed or by direct payment by the hospital.

[53 FR 1627, Jan. 21, 1988, as amended at 53 FR 38532, Sept. 30, 1988; 54 FR 36495, Sept. 1, 1989; 56 FR 43449, Aug. 30, 1991; 57 FR 3016, Jan. 27, 1992; 59 FR 36712, July 19, 1994; 59 FR 45400, Sept. 1, 1994; 66 FR 41387, Aug. 7, 2001; 67 FR 56049, Aug. 30, 2002; 68 FR 45470, Aug. 1, 2003; 69 FR 66977, Nov. 15, 2004]

§ 412.120 Reductions to total payments.

(a) *Deductible and coinsurance.* Subject to paragraph (a)(2) of this section, the total Medicare payments otherwise payable to a hospital are reduced by the applicable deductible and coinsurance amounts related to inpatient hospital services as determined in accordance with §§ 409.82, 409.83, and 409.87 of this chapter.

(b) *Payment by workers' compensation, automobile medical, no-fault or liability insurance or an employer group health plan primary to Medicare.* If workers' compensation, automobile medical, no-fault, or liability insurance or an employer group health plan which is primary to Medicare pays in full or in part, the Medicare payment is determined in accordance with the following guidelines:

(1) If workers' compensation pays, in accordance with the applicable provisions of §§ 405.316 through 405.321 of this chapter.

(2) If automobile medical, no-fault, or liability insurance pays, in accordance with the applicable provisions of §§ 405.322 through 405.325 of this chapter.

(3) If an employer group health plan which is primary to Medicare pays for services to ESRD beneficiaries, in accordance with the applicable provisions of §§ 405.326 through 405.329 of this chapter.

(4) If an employer group health plan which is primary to Medicare pays for services to employees age 65–69 and their spouses age 65–69, in accordance with the applicable provisions of §§ 405.340 through 405.344 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 55 FR 36071, Sept. 4, 1990; 56 FR 573, Jan. 7, 1991; 57 FR 39825, Sept. 1, 1992]

§ 412.125 Effect of change of ownership on payments under the prospective payment systems.

When a hospital's ownership changes, as described in § 489.18 of this chapter, the following rules apply:

(a) Payment for the operating and capital-related costs of inpatient hospital services for each patient, including outlier payments, as provided in § 412.112, and payments for hemophilia clotting factor costs under § 412.115(b), are made to the entity that is the legal owner on the date of discharge. Payments are not prorated between the buyer and seller.

(1) The owner on the date of discharge is entitled to submit a bill for all inpatient hospital services furnished to a beneficiary regardless of when the beneficiary's coverage began or ended during a stay, or of how long the stay lasted.

(2) Each bill submitted must include all information necessary for the intermediary to compute the payment amount, whether or not some of that information is attributable to a period during which a different party legally owned the hospital.

(b) Other payments under § 412.113 and payments for bad debts as described in § 412.115(a), are made to each owner or operator of the hospital (buyer and seller) in accordance with

the principles of reasonable cost reimbursement.

[50 FR 12741, Mar. 29, 1985, as amended at 56 FR 43449, Aug. 30, 1991]

§412.130 Retroactive adjustments for incorrectly excluded hospitals and units.

(a) *Hospitals for which adjustment is made*. The intermediary makes the payment adjustment described in paragraph (b) of this section for the following hospitals:

(1) A hospital that was excluded from the prospective payment systems specified in §412.1(a)(1) or paid under the prospective payment system specified in §412.1(a)(3), as a new rehabilitation hospital for a cost reporting period beginning on or after October 1, 1991 based on a certification under §412.23(b)(8) of this part regarding the inpatient population the hospital planned to treat during that cost reporting period, if the inpatient population actually treated in the hospital during that cost reporting period did not meet the requirements of §412.23(b)(2).

(2) A hospital that has a unit excluded from the prospective payment systems specified in §412.1(a)(1) or paid under the prospective payment system specified in §412.1(a)(3), as a new rehabilitation unit for a cost reporting period beginning on or after October 1, 1991, based on a certification under §412.30(a) regarding the inpatient population the hospital planned to treat in that unit during the period, if the inpatient population actually treated in the unit during that cost reporting period did not meet the requirements of §412.23(b)(2).

(3) A hospital that added new beds to its existing rehabilitation unit for a cost reporting period beginning on or after October 1, 1991 based on a certification under §412.30(c) regarding the inpatient population the hospital planned to treat in these new beds during that cost reporting period, if the inpatient population actually treated in the new beds during that cost reporting period did not meet the requirements of §412.23(b)(2).

(b) *Adjustment of payment*. (1) For cost reporting periods beginning before January 1, 2002, the intermediary adjusts the payment to the hospitals described in paragraph (a) of this section as follows:

(i) The intermediary calculates the difference between the amounts actually paid during the cost reporting period for which the hospital, unit, or beds were first excluded as a new hospital, new unit, or newly added beds under subpart B of this part, and the amount that would have been paid under the prospective payment systems specified in §412.1(a)(1) for services furnished during that period.

(ii) The intermediary makes a retroactive adjustment for the difference between the amount paid to the hospital based on the exclusion and the amount that would have been paid under the prospective payment systems specified in §412.1(a)(1).

(2) For cost reporting periods beginning on or after January 1, 2002, the intermediary adjusts the payment to the hospitals described in paragraph (a) of this section as follows:

(i) The intermediary calculates the difference between the amounts actually paid under subpart P of this part during the cost reporting period for which the hospital, unit, or beds were first classified as a new hospital, new unit, or newly added beds under subpart B of this part, and the amount that would have been paid under the prospective payment systems specified in §412.1(a)(1) for services furnished during that period.

(ii) The intermediary makes a retroactive adjustment for the difference between the amount paid to the hospital under subpart P of this part and the amount that would have been paid under the prospective payment systems specified in §412.1(a)(1).

[56 FR 43241, Aug. 30, 1991, as amended at 57 FR 39825, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994; 60 FR 45848, Sept. 1, 1995; 66 FR 41387, Aug. 7, 2001; 70 FR 66977, Nov. 15, 2005]

Subparts I–J [Reserved]

Subpart K—Prospective Payment System for Inpatient Operating Costs for Hospitals Located in Puerto Rico

SOURCE: 52 FR 33058, Sept. 1, 1987, unless otherwise noted.

§ 412.200 General provisions.

Beginning with discharges occurring on or after October 1, 1987, hospitals located in Puerto Rico are subject to the rules governing the prospective payment system for inpatient operating costs. Except as provided in this subpart, the provisions of subparts A, B, C, F, G, and H of this part apply to hospitals located in Puerto Rico. Except for § 412.60, which deals with DRG classification and weighting factors, the provisions of subparts D and E, which describe the methodology used to determine prospective payment rates for inpatient operating costs for hospitals, do not apply to hospitals located in Puerto Rico. Instead, the methodology for determining prospective payment rates for inpatient operating costs for these hospitals is set forth in §§ 412.204 through 412.212.

[57 FR 39825, Sept. 1, 1992]

§ 412.204 Payment to hospitals located in Puerto Rico.

(a) *FY 1988 through FY 1997*. For discharges occurring on or after October 1, 1987 and before October 1, 1997, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

(1) 75 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.210; and

(2) 25 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

(b) *FY 1998 through March 31, 2004*. For discharges occurring on or after October 1, 1997 and before April 1, 2004, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

(1) 50 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.210; and

(2) 50 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

(c) *Period of April 1, 2004 through September 31, 2004*. For discharges occurring on or after April 1, 2004 and before October 1, 2004, payment for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

(1) 37.5 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.210; and

(2) 62.5 percent of the national prospective payment rate for inpatient operating costs, as determined under § 412.212.

(d) *FY 2005 and thereafter*. For discharges occurring on or after October 1, 2004, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

(1) 25 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.211; and

(2) 75 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

[62 FR 46030, Aug. 29, 1997, as amended at 69 FR 49247, Aug. 11, 2004]

§ 412.208 Puerto Rico rates for Federal fiscal year 1988.

(a) *General rule*. CMS determines the Puerto Rico adjusted DRG prospective payment rate for inpatient operating costs for each inpatient hospital discharge occurring in Federal fiscal year 1988 for a prospective payment hospital. These rates are determined as described in paragraphs (b) through (i) of this section.

(b) *Determining target amounts*. For each hospital subject to the prospective payment system for inpatient operating costs, CMS determines the Medicare target amount, as described in § 413.40(c) of this chapter, for the hospital's cost reporting period beginning in fiscal year 1987. Revisions in

the target amounts made subsequent to establishment of the standardized amounts under paragraph (d) of this section do not affect the standardized amounts.

(c) *Updating the target amounts for fiscal year 1988.* CMS updates each target amount determined under paragraph (b) of this section for fiscal year 1988 by prorating the applicable percentage increase (as defined in §412.63(f) of this chapter) for fiscal year 1988 to the midpoint of fiscal year 1988 (April 1, 1988).

(d) *Standardizing amounts.* CMS standardizes the amount updated under paragraph (c) of this section for each hospital by—

(1) Adjusting for variations in case mix among hospitals;

(2) Excluding an estimate of indirect medical education costs;

(3) Adjusting for area variations in hospital wage levels; and

(4) Excluding an estimate of the payments for hospitals that serve a disproportionate share of low-income patients.

(e) *Computing urban and rural averages.* CMS computes separate discharge-weighted averages of the standardized amounts determined under paragraph (d) of this section for urban and rural hospitals in Puerto Rico.

(f) *Geographic classification.* (1) For purposes of this paragraph (e) of this section, the following definitions apply:

(i) The term *urban area* means a Metropolitan Statistical Area (MSA), as defined by the Executive Office of Management and Budget.

(ii) The term *large urban area* means an MSA with a population of more than 1,000,000.

(iii) The term *rural area* means any area outside an urban area.

(2) A hospital classified as rural is deemed to be urban and receives the urban Puerto Rico payment amount if the county in which it is located meets the following criteria:

(i) At least 95 percent of the perimeter of the rural county is contiguous with urban counties.

(ii) The county was reclassified from an urban area to a rural area after April 20, 1983, as described in §412.62(f)(1)(iv).

(iii) At least 15 percent of employed workers in the county commute to the central county of one of the adjacent MSAs.

(g) *Reducing for value of outlier payments.* CMS reduces each of the average standardized amounts determined under paragraphs (c) through (e) of this section by a proportion equal to the proportion (estimated by CMS) of the total amount of payments based on DRG prospective payment rates that are additional payments to hospitals located in Puerto Rico for outlier cases under subpart F of this part.

(h) *Computing Puerto Rico rates established under the prospective payment system for inpatient operating costs for urban and rural hospitals.* For each discharge classified within a DRG, CMS establishes a Puerto Rico prospective payment rate, as follows:

(1) For hospitals located in an urban area, the rate equals the product of—

(i) The average standardized amount (computed under paragraphs (c) through (g) of this section) for hospitals located in an urban area; and

(ii) The weighting factor determined under §412.60(b) for that DRG.

(2) For hospitals located in a rural area, the rate equals the product of—

(i) The average standardized amount (computed under paragraphs (c) through (g) of this section) for hospitals located in a rural area; and

(ii) The weighting factor determined under §412.60(b) for that DRG.

(i) *Adjusting for different area wage levels.* CMS adjusts the proportion (as estimated by CMS from time to time) of Puerto Rico rates computed under paragraph (h) of this section that are attributable to wages and labor-related costs, for area differences in hospital wage levels, by a factor (established by CMS) reflecting the relative hospital wage level in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (f) of this section) of the hospital compared to the national average hospital wage level.

[52 FR 33058, Sept. 1, 1987; 52 FR 35350, Sept. 18, 1987, as amended at 53 FR 38533, Sept. 30, 1988; 57 FR 39825, Sept. 1, 1992]

§ 412.210 Puerto Rico rates for Federal fiscal years 1989 through 2003.

(a) *General rule.* (1) CMS determines the Puerto Rico adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge occurring in Federal fiscal years 1989 through 2003 that involves inpatient hospital services of a hospital in Puerto Rico subject to the prospective payment system for which payment may be made under Medicare Part A.

(2) The rate is determined for hospitals located in large urban, other urban, or rural areas within Puerto Rico, as described in paragraphs (b) through (e) of this section.

(b) *Geographic classifications.* (1) For purposes of this section, the definitions set forth in § 412.208(f)(1) apply.

(2) For discharges occurring on or after October 1, 1988, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greatest number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs. These EOMB standards are set forth in the notice of final standards for classification of MSAs published in the FEDERAL REGISTER on January 3, 1980 (45 FR 956), and available from CMS, East High Rise Building, Room 132, 6325 Security Boulevard, Baltimore, Maryland 21207.

(3) For discharges occurring on or after October 1, 1988, for hospitals that consist of two or more separately located inpatient hospital facilities, the national adjusted prospective payment rate for inpatient operating costs is based on the geographic location of the hospital at which the discharge occurs.

(c) *Updating previous standardized amounts.* CMS computes separate average standardized amounts for hospitals in large urban, other urban, and rural areas within Puerto Rico equal to the respective average standardized amount computed for fiscal year 1988 under § 412.208(e)—

(1) Increased by the applicable percentage changes determined under § 412.63 (g) and (h); and

(2) Reduced by a proportion equal to the proportion (estimated by CMS) of the total amount of prospective payments that are additional payment amounts to hospitals located in Puerto Rico attributable to outlier cases under subpart F of this part.

(d) *Computing Puerto Rico rates for large urban, other urban, and rural hospitals.* For each discharge classified within a DRG, CMS establishes for the fiscal year a Puerto Rico prospective payment rate for inpatient operating costs as follows:

(1) For hospitals located in a large urban or other urban area in Puerto Rico, the rate equals the product of—

(i) The average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in a large urban or other urban area; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(2) For hospitals located in a rural area in Puerto Rico, the rate equals the product of—

(i) The average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in a rural area; and

(ii) The weighting factor (determined under § 412.60(b)) for that DRG.

(e) *Adjusting for different area wage levels.* CMS adjusts the proportion (as estimated by CMS from time to time) of Puerto Rico rates computed under paragraph (d) of this section that is attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS) reflecting the relative hospital wage level in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the Peurto Rico average hospital wage level.

[52 FR 33058, Sept. 1, 1987, as amended at 53 FR 38533, Sept. 30, 1988; 57 FR 39825, Sept. 1, 1992; 62 FR 46030, Aug. 29, 1997; 69 FR 49247, Aug. 11, 2004]

§412.211 Puerto Rico rates for Federal fiscal year 2004 and subsequent fiscal years.

(a) *General rule.* CMS determines the Puerto Rico adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge occurring in Federal fiscal year 2004 and subsequent fiscal years that involves inpatient hospital services of a hospital in Puerto Rico subject to the prospective payment system for which payment may be made under Medicare Part A.

(b) *Geographic classifications.*

(1) For purposes of this section, the following definitions apply:

(i) The term *urban area* means a Metropolitan Statistical Area (MSA) as defined by the Executive Office of Management and Budget.

(ii) The term *rural area* means any area outside of an urban area.

(2) For discharges occurring on or after October 1, 2004, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greater number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs. These EOMB standards are set forth in the notice of final revised standards for classification of MSAs published in the FEDERAL REGISTER on December 27, 2000 (65 FR 82228), announced by EOMB on June 6, 2003, and available from CMS, 7500 Security Boulevard, Baltimore, Maryland 21244.

(c) *Computing the standardized amount.* CMS computes a Puerto Rico standardized amount that is applicable to all hospitals located in all areas, increased by the applicable percentage change specified in §412.64(d)(1).

(d) *Computing Puerto Rico Federal rates for inpatient operating costs for hospitals located in all areas.* For each discharge classified within a DRG, CMS establishes for the fiscal year a Puerto Rico prospective payment rate for inpatient operating costs equal to the product of—

(1) The average standardized amount for the fiscal year for hospitals located in all areas; and

(2) The weighting factor determined under §412.60(b) for that DRG.

(e) *Adjusting for different area wage levels.* CMS adjusts the proportion of the Puerto Rico rate for inpatient operating costs that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the Puerto Rico average level of hospital wages and wage-related costs. The adjustment specified in this paragraph (e) also takes into account the earnings and paid hours of employment by occupational category.

(1) The wage index is updated annually.

(2) CMS determines the proportion of the Puerto Rico rate that is attributable to wages and labor-related costs from time to time, employing a methodology that is described in the annual update of the prospective payment system for payment of inpatient hospital operating costs published in the FEDERAL REGISTER.

(3) For discharges occurring on or after October 1, 2004, CMS employs 62 percent as the proportion of the rate that is adjusted for the relative level of hospital wages and wage-related costs, unless employing that percentage would result in lower payments for the hospital than employing the proportion determined under the methodology described in paragraph (e)(2) of this section.

(f) *Adjusting the wage index to account for commuting patterns of hospital workers.*

(1) *General criteria.* For discharges occurring on or after October 1, 2004, CMS adjusts the hospital wage index for hospitals located in qualifying areas to recognize the commuting patterns of hospital employees. A qualifying area

is an area that meets all of the following criteria:

(i) Hospital employees in the area commute to work in an MSA (or MSAs) with a wage index (or wage indices) higher than the wage index of the area.

(ii) At least 10 percent of the county's hospital employees commute to an MSA (or MSAs) with a higher wage index (or wage indices).

(iii) The 3-year average hourly wage of the hospital(s) in the area equals or exceeds the 3-year average hourly wage of all hospitals in the MSA or rural area in which the county is located.

(2) *Amount of adjustment.* A hospital located in an area that meets the criteria under paragraphs (f)(1)(i) through (f)(1)(iii) of this section will receive an increase in its wage index that is equal to a weighted average of the difference between the prereclassified wage index of the MSA (or MSAs) with the higher wage index (or wage indices) and the prereclasssified wage index of the qualifying area, weighted by the overall percentage of the hospital employees residing in the qualifying area who are employed in any MSA with a higher wage index.

(3) *Process for determining the adjustment.*

(i) CMS will use the most accurate data available, as determined by CMS, to determine the out-migration percentage for each area.

(ii) CMS will include, in its annual proposed and final notices of updates to the hospital inpatient prospective payment system, a listing of qualifying areas and the hospitals that are eligible to receive the adjustment to their wage indexes for commuting hospital employees, and the wage index increase applicable to each qualifying area.

(iii) Any wage index adjustment made under this paragraph (f) is effective for a period of 3 fiscal years, except that hospitals in a qualifying county may elect to waive the application of the wage index adjustment. A hospital may waive the application of the wage index adjustment by notifying CMS in writing within 45 days after the publication in the FEDERAL REGISTER of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system.

(iv) A hospital in a qualifying area that receives a wage index adjustment under this paragraph (f) is not eligible for reclassification under Subpart L of this part.

[69 FR 49248, Aug. 11, 2004]

§ 412.212 National rate.

(a) *General rule.* For purposes of payment to hospitals located in Puerto Rico, the national prospective payment rate for inpatient operating costs is determined as described in paragraphs (b) through (d) of this section.

(b) *Computing Puerto Rico standardized amounts.* (1) For Federal fiscal years before FY 2004, CMS computes a discharge-weighted average of the—

(i) National urban adjusted standardized amount determined under § 412.63(j)(1); and

(ii) National rural adjusted average standardized amount determined under § 412.63(j)(2)(i).

(2) For fiscal years 2004 and subsequent fiscal years, CMS computes a discharge-weighted average of the national adjusted standardized amount determined under § 412.64(e).

(c) *Computing a national rate.* For each discharge classified within a DRG, the national rate equals the product of—

(1) The national average standardized amount computed under paragraph (b) of this section; and

(2) The weighting factor (determined under § 412.60(b)) for that DRG.

(d) *Adjusting for different area wage levels.* CMS adjusts the proportion (as estimated by CMS from time to time) of the national rate computed under paragraph (c) of this section that is attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

[52 FR 33058, Sept. 1, 1987, as amended at 53 FR 38533, Sept. 30, 1988; 57 FR 39825, Sept. 1, 1992; 69 FR 49248, Aug. 11, 2004]

§ 412.220 Special treatment of certain hospitals located in Puerto Rico.

Subpart G of this part sets forth rules for special treament of certain facilities under the prospective payment

system for inpatient operating costs. The following sections in subpart G of this part do not apply to hospitals located in Puerto Rico:

(a) Section 412.92, sole community hospitals.

(b) Section 412.96, referral centers.

[52 FR 33058, Sept. 1, 1987, as amended at 57 FR 39825, Sept. 1, 1992]

Subpart L—The Medicare Geographic Classification Review Board

SOURCE: 55 FR 36766, Sept. 6, 1990, unless otherwise noted.

CRITERIA AND CONDITIONS FOR REDESIGNATION

§412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

(a) *General.* (1) *Purposes.* Except as specified in paragraph (a)(5)—

(i) For fiscal years prior to fiscal year 2005, an individual hospital may be redesignated from a rural area to an urban area, from a rural area to another rural area, or from an urban area to another urban area for the purposes of using the other area's standardized amount for inpatient operating costs, the wage index value, or both.

(ii) Effective for fiscal year 2005 and subsequent fiscal years, an individual hospital may be redesignated from an urban area to another urban area, from a rural area to another rural area, or from a rural area to another urban area for the purposes of using the other area's wage index value.

(2) *Proximity.* Except as provided in paragraph (a)(3) of this section, to be redesignated to another rural area or an urban area, a hospital must demonstrate a close proximity to the area to which it seeks redesignation by meeting the criteria in paragraph (b) of this section, and submitting data requested under paragraph (c) of this section.

(3) *Special rules for sole community hospitals and rural referral centers.* To be redesignated under the special rules in this paragraph, a hospital must be a sole community hospital or a rural referral center as of the date of the MGCRB's review.

(i) A hospital that is a rural referral center, a sole community hospital, or both does not have to demonstrate a close proximity to the area to which it seeks redesignation.

(ii) If a hospital that is a rural referral center, a sole community hospital, or both qualifies for urban redesignation, it is redesignated to the urban area that is closest to the hospital. If the hospital is closer to another rural area than to any urban area, it may seek redesignation to either the closest rural or the closest urban area.

(iii) If a sole community hospital or rural referral center loses its special status as a result of redesignation, the hospital is considered to retain its special status for the purpose of applicability of the special rules in paragraph (a)(3) of this section.

(iv) A hospital that is redesignated under paragraph (a)(3) of this section may not be redesignated in the same fiscal year under paragraph (a)(2) of this section.

(4) *Application of criteria.* In applying the numeric criteria contained in paragraphs (b)(1), (b)(2), (d)(1)(iii), (d)(1)(iv)(A), and (d)(1)(iv)(B) of this section, rounding of numbers to meet the mileage or qualifying percentage standards is not permitted.

(5) *Limitations on redesignation.* The following limitations apply to redesignation:

(i) An individual hospital may not be redesignated to another area for purposes of the wage index if the pre-reclassified average hourly wage for that area is lower than the pre-reclassified average hourly wage for the area in which the hospital is located.

(ii) A hospital may not be redesignated to more than one area.

(iii) An urban hospital that has been granted redesignation as rural under §412.103 cannot receive an additional reclassification by the MGCRB based on this acquired rural status for a year in which such redesignation is in effect.

(iv) Beginning with wage index reclassification applications for FY 2003, if a hospital is already reclassified to a given geographic area for wage index

purposes for a 3-year period, and submits an application for reclassification to the same area for either the second or third year of the 3-year period, that application will not be approved.

(b) *Proximity criteria.* A hospital demonstrates a close proximity with the area to which it seeks redesignation if one of the following conditions applies:

(1) The distance from the hospital to the area is no more than 15 miles for an urban hospital and no more than 35 miles for a rural hospital.

(2) At least 50 percent of the hospital's employees reside in the area.

(c) *Appropriate proximity data.* For redesignation to an area, the hospital must submit appropriate data relating to its proximity to that area.

(1) To demonstrate proximity to the area, the hospital must submit evidence of the shortest route over improved roads to the area and the distance of that route.

(2) For employee address data, the hospital must submit current payroll records that include information that establishes the home addresses by zip code of its employees.

(d) *Use of urban or other rural area's wage index*—(1) *Criteria for use of area's wage index.* Except as provided in paragraphs (d)(3) and (d)(4) of this section, to use an area's wage index, a hospital must demonstrate the following:

(i) The hospital's incurred wage costs are comparable to hospital wage costs in an urban or other rural area;

(ii) The hospital has the necessary geographic relationship as specified in paragraphs (a) and (b) of this section;

(iii) One of the following conditions apply:

(A) With respect to redesignations for Federal fiscal years 1994 through 2001, the hospital's average hourly wage is at least 108 percent of the average hourly wage of hospitals in the area in which the hospital is located;

(B) With respect to redesignations for Federal fiscal years 2002 through 2005, the hospital's average hourly wage is, in the case of a hospital located in a rural area, at least 106 percent and in the case of a hospital located in an urban area, at least 108 percent of the average hourly wage of hospitals in the area in which the hospital is located; or

(C) With respect to redesignations for Federal fiscal year 2006 and subsequent years, the hospital's average hourly wage is, in the case of a hospital located in a rural area, at least 106 percent and in the case of a hospital located in an urban area, at least 108 percent of the average hourly wage of all other hospitals in the area in which the hospital is located;

(iv) One of the following conditions apply:

(A) For redesignations effective before fiscal year 1999, the hospital's average hourly wage weighted for occupational categories is at least 90 percent of the average hourly wages of hospitals in the area to which it seeks redesignation.

(B) With respect to redesignations for fiscal year 1994 through 2001, the hospital's average hourly wage is equal to at least 84 percent of the average hourly wage of hospitals in the area to which it seeks redesignation.

(C) With respect to redesignations for fiscal year 2002 and later years, the hospital's average hourly wage is equal to, in the case of a hospital located in a rural area, at least 82 percent, and in the case of a hospital located in an urban area, at least 84 percent of the average hourly wage of hospitals in the area to which it seeks redesignation.

(2) *Appropriate wage data.* For a wage index change, the hospital must submit appropriate wage data as follows:

(i) For redesignations effective through FY 2002:

(A) For hospital-specific data, the hospital must provide data from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes during the fiscal year prior to the fiscal year for which the hospital requests reclassification.

(B) For data for other hospitals, the hospital must provide data concerning the average hourly wage in the area in which the hospital is located and the average hourly wage in the area to which the hospital seeks reclassification. The wage data are taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes during the fiscal year prior to the fiscal year for

which the hospital requests reclassification.

(ii) For redesignations effective beginning FY 2003:

(A) For hospital-specific data, the hospital must provide a weighted 3-year average of its average hourly wages using data from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes. However, for the limited purpose of qualifying for geographic reclassification based on wage data from cost reporting periods beginning prior to FY 2000, a hospital may request that its wage data be revised if the hospital is in an urban area that was subject to the rural floor for the period during which the wage data the hospital wishes to revise were used to calculate its wage index.

(B) For data for other hospitals, the hospital must provide a weighted 3-year average of the average hourly wage in the area in which the hospital is located and a weighted 3-year average of the average hourly wage in the area to which the hospital seeks reclassification. The wage data are taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes.

(iii) For applications submitted for reclassifications effective in FYs 2006 through 2008, a campus of a multicampus hospital may seek reclassification to a CBSA in which another campus(es) is located. If the campus is seeking reclassification to a CBSA in which another campus(es) is located, as part of its reclassification request, the requesting entity may submit the composite wage data for the entire multicampus hospital as its hospital-specific data.

(iv) For purposes of this paragraph (d)(2), if a new owner does not accept assignment of the existing hospital's provider agreement in accordance with § 489.18 of this chapter, the hospital will be treated as a new provider with a new provider number. In this case, the wage data associated with the previous hospital's provider number cannot be used in calculating the new hospital's 3-year average hourly wage. Once a new hospital has accumulated at least 1 year of wage data, it is eligible to apply for reclassification on the basis of those data.

(3) *Rural referral center exceptions.* (i) If a hospital was ever a rural referral center, it does not have to demonstrate that it meets the average hourly wage criterion set forth in paragraph (d)(1)(iii) of this section.

(ii) If a hospital was ever a rural referral center, it is required to meet only the criterion that applies to rural hospitals under paragraph (d)(1)(iv) of this section, regardless of its actual location in an urban or rural area.

(4) *Special dominating hospital exception.* The requirements of paragraph (d)(1)(i) and (d)(1)(iii) of this section do not apply if a hospital meets the following criteria:

(i) Its average hourly wage is at least 108 percent of the average hourly wage of all other hospitals in the area in which the hospital is located.

(ii) It pays at least 40 percent of the adjusted uninflated wages in the MSA.

(iii) It was approved for redesignation under this paragraph (d) for each year from fiscal year 1992 through fiscal year 1997.

[55 FR 36766, Sept. 6, 1990, as amended at 56 FR 25488, June 4, 1991; 57 FR 39825, Sept. 1, 1992; 59 FR 45399, Sept. 1, 1994; 60 FR 45848, Sept. 1, 1995; 62 FR 46031, Aug. 29, 1997; 63 FR 26357, May 12, 1998; 65 FR 47108, Aug. 1, 2000; 66 FR 39934, Aug. 1, 2001; 68 FR 45470, Aug. 1, 2003; 68 FR 45470, Aug. 1, 2003; 69 FR 49249, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 69 FR 78529, Dec. 30, 2004; 70 FR 47484, Aug. 12, 2005; 70 FR 57162, Sept. 30, 2005]

§ 412.232 Criteria for all hospitals in a rural county seeking urban redesignation.

(a) *Criteria.* For all hospitals in a rural county to be redesignated to an urban area, the following conditions must be met:

(1) The county in which the hospitals are located—

(i) For fiscal years prior to fiscal year 2006, must be adjacent to the MSA or NECMA to which they seek redesignation.

(ii) For fiscal years beginning with fiscal year 2006, must be adjacent to the MSA to which they seek redesignation.

(2) All hospitals in a rural county must apply for redesignation as a group.

(3) The hospitals must demonstrate that the rural county in which they are located currently meets the criteria for metropolitan character under paragraph (b) of this section and the wage criteria under paragraph (c) of this section.

(4) The hospital may be redesignated only if one of the following conditions is met:

(i) The prereclassified average hourly wage for the area to which they seek redesignation is higher than the prereclassified average hourly wage for the area in which they are currently located.

(ii) For fiscal years prior to fiscal year 2006, the standardized amount for the area to which they seek redesignation is higher than the standardized amount for the area in which they are located.

(b) *Metropolitan character*. (1) For fiscal years prior to FY 2005, the group of hospitals must demonstrate that the county in which the hospitals are located meets the standards for redesignation to an MSA or an NECMA as an outlying county that were published in the FEDERAL REGISTER on March 30, 1990 (55 FR 12154) using Bureau of the Census data or Bureau of Census estimates made after 1990.

(2) For fiscal years beginning with FY 2005, the group of hospitals must demonstrate that the county in which the hospitals are located meets the standards for redesignation to an MSA as an outlying county that were published in the FEDERAL REGISTER on December 27, 2000 (65 FR 82228) using Census Bureau data or Census Bureau estimates made after 2000.

(c) *Wage criteria*. In applying the following numeric criteria, rounding of numbers to meet the qualifying percentages is not permitted.

(1) *Aggregate hourly wage*. The aggregate average hourly wage for all hospitals in the rural county must be equal to at least 85 percent of the average hourly wage in the adjacent urban area; or

(2) *Aggregate hourly wage weighted for occupational mix*. For redesignations effective before fiscal year 1999, the aggregate hourly wage for all hospitals in the rural county, weighted for occupational categories, is at least 90 percent of the average hourly wage in the adjacent urban area.

(d) *Appropriate data*. (1) *Metropolitan character*. (i) To meet the criteria in paragraph (b) of this section, the hospitals may submit data, estimates, or projections, made by the Bureau of the Census concerning population density or growth, or changes in designation of urban areas.

(ii) The MGCRB only considers data developed by the Bureau of the Census.

(2) *Appropriate wage data*. The hospitals must submit appropriate data as follows:

(i) For redesignations effective through FY 2002:

(A) For hospital-specific data, the hospitals must provide data from the CMS wage survey used to construct the wage index in effect for prospective payment purposes during the fiscal year prior to the fiscal year for which the hospitals request reclassification.

(B) For data for other hospitals, the hospitals must provide the following:

(*1*) The average hourly wage in the adjacent area, which is taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes during the fiscal year prior to the fiscal year for which the hospitals request reclassification.

(*2*) Occupational-mix data to demonstrate the average occupational mix for each employment category in the adjacent area. Occupational-mix data can be obtained from surveys conducted by the American Hospital Association.

(ii) For redesignations effective beginning FY 2003:

(A) For hospital-specific data, the hospital must provide a weighted 3-year average of its average hourly wages using data from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes.

(B) For data for other hospitals, the hospital must provide a weighted 3-year average of the average hourly wage in the area in which the hospital is located and a weighted 3-year average of the average hourly wage in the area to which the hospital seeks reclassification. The wage data are taken from the CMS hospital wage survey

used to construct the wage index in effect for prospective payment purposes.

[55 FR 36766, Sept. 6, 1990, as amended at 57 FR 39826, Sept. 1, 1992; 58 FR 46339, Sept. 1, 1993; 59 FR 45399, Sept. 1, 1994; 60 FR 45849, Sept. 1, 1995; 62 FR 46031, Aug. 29, 1997; 66 FR 39934, Aug. 1, 2001; 69 FR 49249, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

§412.234 Criteria for all hospitals in an urban county seeking redesignation to another urban area.

(a) *General criteria.* For all prospective payment hospitals in an urban county to be redesignated to another urban area, the following conditions must be met:

(1) All hospitals in an urban county must apply for redesignation as a group.

(2) The county in which the hospitals are located must be adjacent to the urban area to which they seek redesignation.

(3) (i) For Federal fiscal years before fiscal year 2006, the counties in which the hospitals are located must be part of the Consolidated Metropolitan Statistical Area (CMSA) that includes the urban area to which they seek redesignation.

(ii) For fiscal year 2006, hospitals located in counties that are in the same Combined Statistical Area (CSA) (under the MSA definitions announced by the OMB on June 6, 2003) as the urban area to which they seek redesignation; or in the same Consolidated Metropolitan Statistical Area (CMSA) (under the standards published by the OMB on March 30, 1990) as the urban area to which they seek designation qualify as meeting the proximity requirements for reclassification to the urban area to which they seek redesignation.

(iii) For Federal fiscal year 2007 and thereafter, hospitals located in counties that are in the same Combined Statistical Area (CSA) (under the MSA definitions announced by the OMB on June 6, 2003) as the urban area to which they seek redesignation qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.

(4) The hospital may be redesignated only if one of the following conditions is met:

(i) The prereclassified average hourly wage for the area to which they seek redesignation is higher than the prereclassified average hourly wage for the area in which they are currently located.

(ii) For fiscal years prior to fiscal year 2005, the standardized amount for the area to which they seek redesignation is higher than the standardized amount for the area in which they are located.

(b) *Wage criteria.* In applying the following numeric criteria, rounding of numbers to meet the qualifying percentages is not permitted.

(1) *Aggregate hourly wage.* The aggregate average hourly wage of all hospitals in the urban county must be at least 85 percent of the average hospital hourly wage in the MSA to which the hospitals in the county seek reclassification; or

(2) *Aggregate hourly wage weighted for occupational mix.* For redesignations effective before fiscal year 1999, the aggregate average hourly wage for all hospitals in the county, weighted for occupational categories, is at least 90 percent of the average hourly wage in the adjacent urban area.

(c) *Appropriate wage data.* The hospitals must submit appropriate wage data as provided for in §412.230(d)(2).

[56 FR 25488, June 4, 1991, as amended at 57 FR 39826, Sept. 1, 1992; 58 FR 46339, Sept. 1, 1993; 60 FR 45849, Sept. 1, 1995; 62 FR 46031, Aug. 29, 1997; 69 FR 49249, Aug. 11, 2004; 70 FR 47487, Aug. 12, 2005]

§412.235 Criteria for all hospitals in a State seeking a statewide wage index redesignation.

(a) *General criteria.* For all prospective payment system hospitals in a State to be redesignated to a statewide wage index, the following conditions must be met:

(1) All prospective payment system hospitals in the State must apply as a group for reclassification to a statewide wage index through a signed single application.

(2) All prospective payment system hospitals in the State must agree to the reclassification to a statewide wage index through a signed affidavit on the application.

(3) All prospective payment system hospitals in the State must agree, through an affidavit, to withdrawal of an application or to termination of an approved statewide wage index reclassification.

(4) All hospitals in the State must waive their rights to any wage index classification that they would otherwise receive absent the statewide wage index classification, including a wage index that any of the hospitals might have received through individual geographic reclassification.

(5) New hospitals that open within the State prior to the deadline for submitting an application for a statewide wage index reclassification (September 1), regardless of whether a group application has already been filed, must agree to the use of the statewide wage index as part of the group application. New hospitals that open within the State after the deadline for submitting a statewide wage index reclassification application or during the approved reclassification period will be considered a party to the statewide wage index application and reclassification.

(b) *Effect on payments.*

(1) An individual hospital within the State may receive a wage index that could be higher or lower under the statewide wage index reclassification in comparison to its otherwise redesignated wage index.

(2) Any new prospective payment system hospital that opens in the State during the effective period of an approved statewide wage index reclassification will be designated to receive the statewide wage index for the duration of that period.

(c) *Terms of the decision.*

(1) A decision by the MGCRB on an application for a statewide wage index reclassification will be effective for 3 years beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year following the Federal fiscal year in which the hospitals filed a complete application.

(2) The procedures and timeframes specified in § 412.273 apply to withdrawals of applications for redesignation to a statewide wage index and terminations of approved statewide wage index reclassifications, including the requirement that, to withdraw an application or terminate an approved reclassification, the request must be made in writing by all hospitals that are party to the application, except hospitals reclassified into the State for purposes of receiving the statewide wage index.

[66 FR 39935, Aug. 1, 2001]

COMPOSITION AND PROCEDURES

§ 412.246 MGCRB members.

(a) *Composition.* The Medicare Geographical Classification Review Board (MGCRB) consists of five members, including a Chairman, all of whom are appointed by the Secretary. The members include two members who are representative of prospective payment system hospitals located in rural areas, and at least one individual who is knowledgeable in analyzing the costs of inpatient hospital services.

(b) *Term of office.* The term of office for an MGCRB member may not exceed 3 years. A member may serve more than one term. The Secretary may terminate a member's tenure prior to its full term.

[55 FR 36766, Sept. 6, 1990, as amended at 61 FR 46224, Aug. 30, 1996; 61 FR 51217, Oct. 1, 1996]

§ 412.248 Number of members needed for a decision or a hearing.

(a) *A quorum.* A quorum, consisting of at least a majority of the MGCRB members, one of whom is representative of rural hospitals if possible, is required for making MGCRB decisions.

(b) *Number of members for a hearing.* If less than a quorum is present for an oral hearing, the chairman with the consent of the hospital may allow those members present to conduct the hearing and to prepare a recommended decision, which is then submitted to a quorum.

§ 412.250 Sources of MGCRB's authority.

(a) *Compliance.* The MGCRB, in issuing decisions under section 1886(d)(10)(C) of the Act, complies with all the provisions of title XVIII and related provisions of the Act and implementing regulations, including the criteria and conditions located at § 412.230

through § 412.236, issued by the Secretary under the authority of section 1886(d)(10)(D) of the Act; and CMS Rulings issued under the authority of the Administrator.

(b) *Affords great weight.* The MGCRB affords great weight to other interpretive rules, general statements of policy and rules of agency organization, procedure, and practice established by CMS.

[55 FR 36766, Sept. 6, 1990, as amended at 56 FR 25488, June 4, 1991]

§ 412.252 Applications.

(a) *By one hospital.* An individual prospective payment system hospital seeking redesignation to a different rural or urban area has the right to submit an application to the MGCRB.

(b) *By a group of hospitals.* A group of hospitals has the right to submit an application to the MGCRB requesting redesignation of all prospective payment hospitals in a county if all prospective payment hospitals located in a county agree to the request.

[55 FR 36766, Sept. 6, 1990, as amended at 69 FR 49250, Aug. 11, 2004]

§ 412.254 Proceedings before MGCRB.

(a) *On-the-record decision.* The MGCRB will ordinarily issue an on-the-record decision without conducting an oral hearing. The MGCRB will issue a decision based upon all documents, data, and other written evidence and comments submitted timely to the MGCRB by the parties.

(b) *Oral hearing.* The MGCRB may hold an oral hearing on its own motion or if a party demonstrates to the MGCRB's satisfaction that an oral hearing is necessary.

§ 412.256 Application requirements.

(a) *Written application.* A request for reclassification must be in writing and must constitute a complete application in accordance with paragraph (b) of this section.

(1) An application must be mailed or delivered to the MGCRB, with a copy to CMS, and may not be submitted through the facsimile (FAX) process or by other electronic means.

(2) A complete application must be received not later than the first day of the 13-month period preceding the Federal fiscal year for which reclassification is requested.

(3) The filing date of an application is the date the application is received by the MGCRB.

(b) *Criteria for a complete application.* An application is complete if the application from an individual hospital or from all hospitals in a county includes the following information:

(1) The Federal fiscal year for which the hospital is applying for redesignation.

(2) Which criteria constitute the basis of the request for reclassification.

(3) An explanation of how the hospital or hospitals meet the relevant criteria in §§ 412.230 through 412.236, including any necessary data to support the application.

(c) *Opportunity to complete a submitted application.* (1) The MGCRB will review an application within 15 days of receipt to determine if the application is complete. If the MGCRB determines that an application is incomplete, the MGCRB will notify the hospital, with a copy to CMS, within the 15 day period, that it has determined that the application is incomplete and may dismiss the application if a complete application is not filed by September 1.

(2) At the request of the hospital, the MGCRB may, for good cause, grant a hospital that has submitted an application by September 1, an extension beyond September 1 to complete its application.

(d) *Appeal of MGCRB dismissal.* (1) The hospital may appeal the MGCRB dismissal to the Administrator within 15 days of the date of the notice of dismissal.

(2) Within 20 days of receipt of the hospital's request for appeal, the Administrator will affirm the dismissal or reverse the dismissal and remand the case to the MGCRB to determine whether reclassification is appropriate.

(e) *Notification of complete application.* When the MGCRB determines that the hospital's application contains all the necessary elements for a complete application, it notifies the hospital in writing, with a copy to CMS, that the application is complete and that the

case may proceed to an MGCRB decision.

[55 FR 36766, Sept. 6, 1990, as amended at 56 FR 25488, June 4, 1991; 62 FR 46031, Aug. 29, 1997; 63 FR 26357, May 12, 1998; 64 FR 41541, July 30, 1999]

§ 412.258 Parties to MGCRB proceeding.

(a) The party or parties to an MGCRB proceeding are the hospital or group of hospitals requesting a change in geographic designation.

(b) CMS has 30 days from the date of receipt of notice of a complete application to submit written comments and recommendations (with a copy to the hospital) for consideration by the MGCRB.

(c) The hospital has 15 days from the date of receipt of CMS's comments to submit written comments to the MGCRB, with a copy to CMS, for the purpose of responding to CMS's comments.

§ 412.260 Time and place of the oral hearing.

If the MGCRB decides that an oral hearing is necessary, it sets the time and place for the hearing and notifies the parties in writing, with a copy to CMS, not less than 10 days before the time scheduled for the hearing. The MGCRB may reschedule, adjourn, postpone, or reconvene the hearing provided that reasonable written notice is given to the parties, with a copy to CMS.

§ 412.262 Disqualification of an MGCRB member.

(a) *Grounds for disqualification*. An MGCRB member may not participate in any decision in a case in which he or she may be prejudiced or partial with respect to a party or has any other interest in the case.

(b) *Request for disqualification*. If a party believes that an MGCRB member should not participate in a decision, the party submits the objection in writing to the MGCRB at its earliest opportunity, explaining the grounds for the request. CMS may also submit such a suggestion to the MGCRB.

(c) *Consideration by the MGCRB member*. The MGCRB member will consider the objection and, at his or her discretion, either will proceed or withdraw.

(d) *Consideration by the MGCRB* If the member does not withdraw, a party may petition the MGCRB for withdrawal and the MGCRB will consider the objection and rule on whether the member may participate in the decision before it decides the case.

§ 412.264 Evidence and comments in MGCRB proceeding.

(a) *Submission by the parties*. Before a decision is issued and during an oral hearing, the parties may present evidence or comments to the MGCRB regarding the matters at issue in the case.

(b) *Content of evidence and comments*. The MGCRB may receive evidence and comments without regard for the rules of evidence applicable to court procedures.

(c) *Ex parte communications*. (1) The members of the MGCRB and its staff may not consult or be consulted by an individual representing the interests of an applicant hospital or by any other individual on any matter in issue before the MGCRB without notice to the hospital or CMS. If such communication occurs, the MGCRB will disclose it to the hospital or CMS, as appropriate, and make it part of the record after the hospital or CMS has had an opportunity to comment. MGCRB members and staff may not consider any information outside the record about matters concerning a hospital's application for reclassification.

(2) The provisions in paragraph (c)(1) of this section do not apply to the following:

(i) Communications among MGCRB members and staff.

(ii) Communications concerning the MGCRB's administrative functions or procedures.

(iii) Requests from the MGCRB to a party or CMS for a document.

(iv) Material that the MGCRB includes in the record after notice and an opportunity to comment.

(d) *MGCRB rulings on evidence and comments*. The MGCRB rules upon the admissibility of evidence and comments and excludes irrelevant, immaterial, or unduly repetitious evidence and comments.

§412.266 Availability of wage data.

A hospital may obtain the average hourly wage data necessary to prepare its application to the MGCRB from FEDERAL REGISTER documents published in accordance with the provisions of §412.8(b).

[60 FR 45849, Sept. 1, 1995]

§412.268 Subpoenas.

(a) *In general.* When reasonably necessary for the full presentation of a case, and only after a pre-decision request for information or data has failed to produce the necessary evidence, either upon its own motion or upon the request of a party, the MGCRB may issue subpoenas for the attendance and testimony of witnesses, for an oral hearing or the production of books, records, correspondence, papers, or other documents that are relevant and material to any matter at issue.

(b) *Content of request.* The request must designate which witnesses or documents are to be produced, and describe addresses or locations with sufficient particularly to permit these witnesses or documents to be found. The request for a subpoena must state the pertinent facts that the party expects to establish by the requested witnesses or documents and whether these facts could be established by other evidence without the use of a subpoena.

(c) *Issuance.* Subpoenas are issued as provided in section 205(d) of the Act.

(d) *Payment for subpoena cost.* CMS pays for the cost of issuing subpoenas and the fees and mileage of any witness who is subpoenaed, as provided in section 205(d) of the Act.

§412.270 Witnesses.

Witnesses at an oral hearing testify under oath or affirmation, unless excused by the MGCRB for cause. The MGCRB may examine the witnesses and may allow the parties or their representatives to also examine any witnesses called.

§412.272 Record of proceedings before the MGCRB.

A complete record of the proceedings before the MGCRB is made in all cases. The record will not be closed until a decision has been issued by the MGCRB. A transcription of an oral hearing will be made at a party's request, at the expense of the requesting party.

§412.273 Withdrawing an application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination.

(a) *Timing of a withdrawal.* The MGCRB allows a hospital, or group of hospitals, to withdraw its application if the request for withdrawal is submitted to the MGCRB during the following time periods:

(1) At any time before the MGCRB issues a decision on the application; or

(2) After the MGCRB issues a decision, provided that the request for withdrawal is received by the MGCRB within 45 days of publication of CMS's annual notice of proposed rulemaking concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed.

(b) *Request for termination of approved 3-year wage index reclassifications.*

(1) A hospital, or a group of hospitals, that has been issued a decision on its application for a 3-year reclassification for wage index purposes only or for redesignation to a statewide wage index and has not withdrawn that application under the procedures specified in paragraph (a) of this section may request termination of its approved 3-year wage index reclassification under the following conditions:

(i) The request to terminate must be received by the MGCRB within 45 days of the publication of the annual notice of proposed rulemaking concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the termination is to apply.

(ii) A request to terminate a 3-year reclassification will be effective only for the full fiscal year(s) remaining in the 3-year period at the time the request is received. Requests for terminations for part of a fiscal year will not be considered.

(2) *Reapplication within the approved 3-year period.*

(i) If a hospital elects to withdraw its wage index application after the

MGCRB has issued its decision, it may cancel its withdrawal in a subsequent year and request the MGCRB to reinstate its wage index reclassification for the remaining fiscal year(s) of the 3-year period.

(ii) A hospital may apply for reclassification for purposes of the wage index to a different area (that is, an area different from the one to which it was originally reclassified for the 3-year period). If the application is approved, the reclassification will be effective for 3 years. Once a 3-year reclassification becomes effective, a hospital may no longer cancel a withdrawal or termination of another 3-year reclassification, regardless of whether the withdrawal or termination request is made within 3 years from the date of the withdrawal or termination.

(iii) In a case in which a hospital with an existing 3-year wage index reclassification applies to be reclassified to another area, its existing 3-year reclassification will be terminated when a second 3-year wage index reclassification goes into effect for payments for discharges on or after the following October 1.

(c) *Written request only.* A request to withdraw an application or terminate an approved reclassification must be made in writing to the MGCRB by all hospitals that are party to the application or reclassification.

(d) *Process for canceling a previous withdrawal or termination.* A hospital may cancel a previous withdrawal or termination by submitting written notice of its intent to the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year, as specified in § 412.256(a)(2).

(e) *Appeal of the MGCRB's denial of a hospital's request for withdrawal.* (1) A hospital may file an appeal of the MGCRB's denial of its request for withdrawal of an application to the Administrator. The appeal must be received within 15 days of the date of the notice of the denial.

(2) Within 20 days of receipt of the hospital's request for appeal, the Administrator affirms or reverses the denial.

[56 FR 25489, June 4, 1991, as amended at 56 FR 43241, Aug. 30, 1991; 57 FR 39826, Sept. 1, 1992; 66 FR 39935, Aug. 1, 2001; 67 FR 50113, Aug. 1, 2002]

§ 412.274 Scope and effect of an MGCRB decision.

(a) *Scope of decision.* The MGCRB may affirm or change a hospital's geographic designation. The MGCRB's decision is based upon the evidence of record, including the hospital's application and other evidence obtained or received by the MGCRB.

(b) *Effective date and term of the decision.* (1) For reclassifications prior to fiscal year 2005, a standardized amount classification change is effective for 1 year beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year following the Federal fiscal year in which the complete application is filed and ending effective at the end of that Federal fiscal year (the end of the next September 30).

(2) A wage index classification change is effective for 3 years beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year in which the complete application is filed.

[55 FR 36766, Sept. 6, 1990, as amended at 62 FR 46031, Aug. 29, 1997; 66 FR 39935, Aug. 1, 2001; 69 FR 49250, Aug. 11, 2004]

§ 412.276 Timing of MGCRB decision and its appeal.

(a) *Timing.* The MGCRB notifies the parties in writing, with a copy to CMS, and issues a decision within 180 days after the first day of the 13-month period preceding the Federal fiscal year for which a hospital has filed a complete application. The hospital has 15 days from the date of the decision to request Administrator review.

(b) *Appeal.* The decision of the MGCRB is final and binding upon the parties unless it is reviewed by the Administrator and the decision is changed by the Administrator in accordance with § 412.278.

[55 FR 36766, Sept. 6, 1990, as amended at 64 FR 41541, July 30, 1999]

§412.278 Administrator's review.

(a) *Hospitals requests for review*. A hospital or group of hospitals dissatisfied with the MGCRB's decision regarding its geographic designation may request the Administrator to review the MGCRB decision. (A hospital or group of hospitals may also request that the Administrator review the MGCRB's dismissal of an application as untimely filed or incomplete, as provided in §412.256(d).)

(b) *Procedures for hospital's request for review*. (1) The hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor. The request must be received by the Administrator within 15 days after the date the MGCRB issues its decision. A request for Administrator review filed by facsimile (FAX) or other electronic means will not be accepted. The hospital must also mail a copy of its request for review to CMS's Hospital and Ambulatory Policy Group.

(2) The request for review may contain proposed findings of fact and conclusions of law, exceptions to the MGCRB's decision, and supporting reasons therefor.

(3) Within 15 days of receipt of the hospital's request for review, CMS may submit to the Administrator, in writing, with a copy to the party, comments and recommendations concerning the hospital's submission.

(4) Within 10 days of receipt of CMS's submission, the hospital may submit in writing, with a copy to CMS, a response to the Administrator.

(c) *Discretionary review by the Administrator*. (1) The Administrator may, at his or her discretion, review any final decision of the MGCRB.

(2) The Administrator promptly notifies the hospital that he or she has decided to review a decision of the MGCRB. The notice of review indicates the particular issues to be considered and includes copies of any comments submitted to the Administrator by CMS staff concerning the MGCRB decision.

(3) Within 15 days of the receipt of the Administrator's notice of review, the hospital may submit a response in writing to the Administrator, with a copy of CMS.

(d) *Criteria for discretionary review*. In deciding whether to review an MGCRB decision, the Administrator normally considers whether it appears that any of the following situations apply:

(1) The MGCRB made an erroneous interpretation of law, regulation, or CMS Ruling.

(2) The MGCRB's decision is not supported by substantial evidence.

(3) The case presents a significant policy issue having a basis in law and regulations, and review is likely to lead to issuance of a CMS Ruling or other directive needed to clarify a provision in the law or regulations.

(4) The decision of the MGCRB requires clarification, amplication, or an alternative legal basis.

(5) The MGCRB has incorrectly extended its authority to a degree not provided for by law, regulation, or CMS Ruling.

(e) *Communication procedures*. All communications between CMS staff and the Administrator concerning the Administrator's review of an MGCRB decision must be in writing. As specified in paragraphs (b) and (c) of this section, copies of comments by CMS staff are sent to applicant hospitals within 15 days of receipt of a hospital's request for review, or, in cases in which the Administrator decides to review a case at his or her discretion, are included with the Administrator's notice of review. In the event there are additional communications between CMS staff and the Administrator concerning MGCRB decisions reviewed by the Administrator under paragraphs (b) or (c) of this section, CMS furnishes copies of the communications to the hospital or group of hospitals.

(f) *Administrator's decision*. (1) The Administrator may not receive or consider any new evidence and must issue a decision based only upon the record as it appeared before the MGCRB and comments submitted under paragraphs (b)(2), (b)(3), (b)(4), (c)(2), and (c)(3) of this section.

(2) The Administrator issues a decision in writing to the party with a copy to CMS—

(i) Not later than 90 days following receipt of the party's request for review, except the Administrator may, at

his or her discretion, for good cause shown, toll such 90 days; or

(ii) Not later than 105 days following issuance of the MGCRB decision in the case of review at the discretion of the Administrator.

(3) The Administrator's decision issued under § 412.278 (a) or (c) is the final Departmental decision, unless it is amended under § 412.278(g). The final Departmental decision is not subject to judicial review.

(4) The Administrator's decision is not subject to judicial review.

(g) *Amendment of Administrator decision*—(1) *Hospital's request for amendment*. The hospital may request the Administrator to amend the decision for the limited purpose of correcting mathematical or computational errors, or to correct the decision if the evidence that was considered in making the decision clearly shows on its face that an error was made. The following procedure is followed:

(i) The hospital's request for amendment must be received by the Administrator within 10 days after the date the Administrator issues a decision. The request for amendment must be in writing, with a copy to CMS.

(ii) The Administrator promptly reviews the hospital's request and amends the decision, if necessary, within 5 days following receipt of the hospital's request for amendment.

(2) *Discretionary review by the Administrator*. Within 15 days following the issuance of the Administrator's decision, the Administrator, at his or her discretion, may amend the decision to correct mathematical or computational errors, or to correct the decision if the evidence that was considered in making the decision clearly shows on its face that an error was made. The Administrator's amended decision is final and is not subject to judicial review.

[55 FR 36766, Sept. 6, 1990, as amended at 56 FR 25489, June 4, 1991; 57 FR 39826, Sept. 1, 1992; 68 FR 45471, Aug. 1, 2003; 70 FR 47487, Aug. 12, 2005]

§ 412.280 Representation.

(a) *General*. A party may be represented by legal counsel or by any other person appointed to act as its representative at any proceeding before the MGCRB or the Administrator.

(b) *Rights of a representative*. A representative appointed by a party may accept or give on behalf of the party any request or notice connected with any proceeding before the MGCRB or the Administrator. A representative is entitled to present evidence and argument as to facts and law in any MGCRB proceeding affecting the party represented and to obtain information to the same extent as the party represented. Notice of any action or decision sent to the representative of a party has the same effect as if it had been sent to the party itself.

Subpart M—Prospective Payment System for Inpatient Hospital Capital Costs

SOURCE: 56 FR 43449, Aug. 30, 1991, unless otherwise noted.

GENERAL PROVISIONS

§ 412.300 Scope of subpart and definition.

(a) *Purpose*. This subpart implements section 1886(g)(1)(A) of the Act by establishing a prospective payment system for inpatient hospital capital-related costs. Under this system, payment is made on the basis described in § 412.304 through § 412.374 for inpatient hospital capital-related costs furnished by hospitals subject to the prospective payment system under subpart B of this part.

(b) *Definition*. For purposes of this subpart, a new hospital means a hospital that has operated (under previous or present ownership) for less than 2 years. The following hospitals are not new hospitals:

(1) A hospital that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(2) A hospital that closes and subsequently reopens.

(3) A hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years.

(4) A hospital that changes its status from a hospital that is excluded from the prospective payment systems to a hospital that is subject to the capital prospective payment systems.

[56 FR 43449, Aug. 30, 1991, as amended at 57 FR 39827, Sept. 1, 1992]

§ 412.302 Introduction to capital costs.

(a) *New capital costs.* New capital costs are allowable Medicare inpatient hospital capital-related costs under subpart G of part 413 of this chapter that are related to assets that were first put in use for patient care after December 31, 1990 (except for such costs deemed to be old capital costs based on prior obligations as described in paragraph (c) of this section) and those allowable capital-related costs related to assets in use prior to December 31, 1990 that are excluded from the definition of old capital costs described in paragraphs (b) (2) through (5) of this section, or are betterment or improvement costs related to those old capital assets.

(b) *Old capital costs.* Except as provided in paragraph (c) of this section with respect to capital obligations that qualify for recognition as old capital, old capital costs are allowable capital-related costs for land and depreciable assets that were put in use for patient care on or before December 31, 1990. However, for a new hospital as defined in § 412.300(b), old capital costs are defined as those allowable capital-related costs for land and depreciable assets that were put in use for patient care on or before the later of December 31, 1990 or the last day of the hospital's base year cost reporting period under § 412.328(a)(2). Old capital costs include the following:

(1) Allowable depreciation on assets based on the useful life guidelines used to determine depreciation expense in the hospital's base period.

(2) Allowable capital-related interest expense. Except as provided below, the amount of allowable capital-related interest expense that will be recognized as old capital is limited to the amount the hospital was legally obligated to pay as of December 31, 1990. Any allowable interest expense in excess of this limitation will be recognized as new capital.

(i) An increase in interest expense is recognized if the increase is due to periodic fluctuations of rates in variable interest rate loans or at the time of conversion from a variable rate loan to a fixed rate loan when no other changes in the terms of the loan are made.

(ii) If the terms of a debt instrument are revised after December 31, 1990, the amount of interest that will be recognized as old capital during the transition cannot exceed the amount that would have been recognized during the same period prior to the revision of the debt instrument.

(iii) If short-term financing was used to acquire old capital assets and the debt is extended or ''rolled-over'', a portion of the extended debt will be recognized as old capital. The portion will equal the ratio of the net book value as of the beginning of the applicable cost reporting period for depreciable assets that were in use in the base year, to the net book value as of the beginning of the base year cost reporting period for those assets. The net book value for the base year will not be adjusted to exclude assets that have been fully depreciated or removed from service since the base year. If the debt is related to specific assets, the ratio will be determined based on the values for those assets. The ratio will exclude assets that were acquired with other identifiable debt instruments. For purposes of this paragraph, short term financing is a debt that becomes due in no later than the earlier of 5 years or half of the average useful life of the assets to which the debt is related.

(iv) If old capital indebtedness is commingled with new capital debt, the allowable interest expense will be apportioned to old capital costs based on the ratio of the portion of the loan principal related to old capital indebtedness to the total loan principal.

(v) Investment income, excluding income from funded depreciation accounts, is used to reduce old capital interest expense based on the ratio of total old capital interest expense to total allowable interest expense in each cost reporting period.

(3) Allowable capital-related lease and rental costs for land and depreciable assets that were obligated as of December 31, 1990.

(i) Lease renewals up to the annual lease payment level obligated as of December 31, 1990 are recognized provided the same asset remains in use, the asset has a useful life of at least 3 years, and the annual lease payment is $1,000 or more for each item or service.

(ii) If a hospital-owned asset is sold or given to another party and that same asset is then leased back by the hospital, the amount of allowable capital-related costs recognized as old capital costs is limited to the amount allowed for that asset in the last cost reporting period that it was owned by the hospital.

(iii) If an entire hospital is leased without assumption of the hospital's asset costs after December 31, 1990, the amount of allowable capital-related costs recognized as old capital costs is limited to the amount allowed for old capital costs in the base year or the last cost reporting period these costs were recognized under this subpart, whichever is later.

(4) The portion of allowable costs for other capital-related expenses (including but not limited to, taxes, insurance, license and royalty fees on depreciable assets) resulting from applying the ratio of the hospital's gross old asset value to total asset value in each cost reporting period.

(5) The appropriate portion of the capital-related costs of related organizations under § 413.17 that would be recognized as old capital costs if these costs had been incurred directly by the hospital.

(6) Obligated capital costs that are recognized as old capital costs in accordance with paragraph (c) of this section.

(7) If a hospital had nonreimbursable costs applicable to an old capital asset as of December 31, 1990 that subsequently become allowable inpatient capital-related costs, the allowable costs for such an asset that are attributable to inpatient hospital services are recognized as old capital costs if a portion of the asset was in use for inpatient hospital care on December 31, 1990 and the costs meet all other provisions for recognition of old capital costs contained in this section.

(c) *Obligated capital costs*—(1) *General rule*. Under the conditions described below, capital-related costs attributable to assets that are put in use after December 31, 1990 may be recognized as old capital costs. Any allowable capital-related costs for these assets that are not recognized as old capital costs are recognized as new capital costs.

(i) *Fixed assets*. The costs of capital-related items and services defined in subpart G of part 413 for which there was a contractual obligation entered into by a hospital or related party with an outside, unrelated party for the construction, reconstruction, lease, rental, or financing of a fixed asset may be recognized as old capital costs if all the following conditions are met:

(A) The obligation must arise from a binding written agreement that was executed on or before December 31, 1990 and that obligates the hospital on or before December 31, 1990.

(B) The capital asset must be put in use for patient care before October 1, 1994 except as provided in paragraph (c)(1)(iv) of this section.

(C) The hospital notifies the intermediary of the existence of obligated capital costs as provided in paragraph (c)(1)(v) of this section.

(D) The amount that is recognized as old capital cost is limited to the lesser of the actual allowable costs when the asset is put in use or the estimated costs of the capital expenditure at the time it was obligated as provided in paragraph (c)(1)(vi) of this section.

(ii) *Moveable equipment*. Moveable equipment is recognized as old capital only if all of the conditions specified in paragraphs (c)(1)(i) (B) through (D) of this section are met and one of the following conditions is met:

(A) There was a binding contractual agreement that was executed on or before December 31, 1990 and obligates the hospital on or before December 31, 1990 for the lease or purchase of the item of equipment on or before December 31, 1990.

(B) There was a binding contractual agreement that was executed on or before December 31, 1990 and obligates the hospital on or before December 31,

1990 for financing the acquisition of the equipment; the item of equipment costs at least $100,000; and the item was specifically listed in an equipment purchase plan approved by the Board of Directors on or before December 31, 1990.

(iii) *Agreements not recognized.* Agreements for planning, design or feasibility that do not commit the hospital to undertake a project are not recognized as obligating capital expenditures for purposes of this subsection.

(iv) *Extension of deadline.* CMS may extend the deadline in paragraph (c)(1)(i)(B) of this section, under which an asset must be put in use for patient care before October 1, 1994, to no later than September 30, 1996 for extraordinary circumstances beyond the hospital's control. Extraordinary circumstances include, but are not limited to, a construction strike or atypically severe weather that significantly delayed completion of a construction project. Normal construction delays do not constitute extraordinary circumstances.

(A) The hospital must submit its request for an extended deadline with documentation of the extraordinary circumstances by the later of January 1, 1993 or 180 days after the extraordinary circumstance.

(B) The intermediary reviews the request and verifies the hospital's documentation, and forwards the request to CMS within 60 days. Within 90 days, CMS notifies the intermediary of its decision and, if an extension is granted, of the revised deadline for putting the asset in use for patient care service.

(v) The hospital must submit to its intermediary the binding agreement and supporting documents that relate to the obligated capital expenditure by the later of October 1, 1992, or within 90 days after the start of the hospital's first cost reporting period beginning on or after October 1, 1991. This documentation must include a project description (including details of any phased construction or financing) and an estimate of costs that were prepared no later than December 31, 1990.

(vi) *Cost limitation*—(A) *Leases, Rentals or Purchases.* The amount of obligated capital costs recognized as old capital costs cannot exceed the amount specified in the lease, rental, or purchase agreement. If moveable equipment is recognized as old capital under paragraph (c)(1)(ii)(B) of this section, the amount recognized as old capital costs cannot exceed the estimated cost identified in the equipment purchase plan approved by the hospital's Board of Directors.

(B) *Construction contracts.* The amount of obligated capital costs recognized as old capital costs cannot exceed the estimated construction costs for the project as of December 31, 1990. Additional costs will be recognized as old capital costs only if the additional costs are directly attributable to changes in life safety codes or other building requirements established by government ordinance that occurred after the project was obligated.

(C) *Financing costs.* The amount of obligated interest expense that will be recognized as old capital costs cannot exceed the amount for which the hospital was legally obligated as of December 31, 1990 or, in the case of financing that is arranged after December 31, 1990 for a capital acquisition that was legally obligated as of December 31, 1990, the amount specified in a detailed financing plan approved by the hospital's Board of Directors prior to January 1, 1991.

(vii) *Determining old capital costs.* (A) The intermediary determines whether the applicable criteria are met for recognition of obligated capital costs as old capital costs and the maximum allowable cost that will be recognized as old capital costs.

(B) The intermediary advises the hospital of its determination by the later of the end of the hospital's first cost reporting period subject to the capital prospective payment system or 9 months after the receipt of the hospital's notification under paragraph (c)(1)(v) of this section.

(C) The actual amount that will be recognized as old capital costs is based on the lesser of the allowable costs for the asset when it is put into patient use or the amounts determined under paragraph (c)(1)(vi) of this section.

(viii) *Multi-phase project.* If the hospital has a multi-phase capital project, the provisions of paragraphs (c)(1) (i)

through (vii) of this section apply independently to each phase of the project.

(2) *Lengthy certificate-of-need process.* (i) If a hospital does not meet the criteria under paragraph (c)(1)(i) or paragraph (c)(1)(ii) of this section, but meets all of the following criteria, the estimated cost for the project as of December 31, 1990 may be recognized as old capital costs:

(A) The hospital is required under State law to obtain preapproval of the capital project or acquisition by a designated State or local planning authority in the State in which it is located.

(B) The hospital filed an initial application for a certificate of need on or before December 31, 1989 that includes a detailed description of the project and its estimated cost and had not received approval or disapproval on or before September 30, 1990. If the hospital received conditional approval on or before September 30, 1990, the hospital's intermediary assesses the nature of the conditions. The hospital will be considered to have received approval for the project as of September 30, 1990 if the intermediary determines that the hospital received sufficient approval for the project to proceed without significant delay.

(C) The hospital expended the lesser of $750,000 or 10 percent of the estimated cost of the project on or before December 31, 1990; and

(D) The hospital put the asset into patient use on or before the later of September 30, 1996 or 4 years from the date the certificate of need was approved.

(ii) The provisions of paragraphs (c)(1) (iv) through (viii) of this section apply to projects that meet the criteria in paragraph (c)(2)(i) of this section.

(3) *Construction in process.* (i) If a hospital that initiates construction on a capital project does not meet the requirements of paragraphs (c)(1)(i) or (ii) or (c)(2)(i) of this section, the project costs may be recognized as old capital costs if all the following conditions are met:

(A) The hospital received any required certificate of need approval on or before December 31, 1990.

(B) The hospital's Board of Directors formally authorized the project with a detailed description of its scope and costs on or before December 31, 1990.

(C) The estimated cost of the project as of December 31, 1990 exceeds 5 percent of the hospital's total patient revenues during its base year.

(D) The capitalized cost that had been incurred for the project as of December 31, 1990 exceeded the lesser of $750,000 or 10 percent of the estimated project cost.

(E) The hospital began actual construction or renovation (''groundbreaking'') on or before March 31, 1991.

(F) The project is completed before October 1, 1994.

(ii) The provisions of paragraphs (c)(1) (iv) through (viii) of this section apply to projects that meet the criteria in paragraph (c)(3)(i) of this section.

(d) *Consistency in cost reporting*—(1) *General rule.* For cost reporting periods beginning on or after October 1, 1991, and before October 1, 2001, the hospital must follow consistent cost finding methods for classifying and allocating capital-related costs, except as otherwise provided in paragraph (d)(4) of this section.

(2) *Old capital costs.* Unless there is a change of ownership, the hospital must continue the same cost finding methods for old capital costs, including its practices for the direct assignment of capital-related costs and its cost allocation bases, that were in effect in the hospital's last cost reporting period ending on or before October 1, 1991. If there is a change of ownership, the new owners may request that the intermediary approve a change in order to be consistent with their established cost finding practices.

(3) *New capital costs.* If a hospital desires to change its cost finding methods for new capital costs, the request for change must be made in writing to the intermediary prior to the beginning of the cost reporting period for which the change is to apply. The request must include justification as to why the change will result in more accurate and more appropriate cost finding. The intermediary will not approve the change unless it determines that there is reasonable justification for the change.

(4) Hospitals may elect the simplified cost allocation methodology under the terms and conditions provided in the instructions for CMS Form 2552.

[56 FR 43449, Aug. 30, 1991, as amended at 57 FR 3016, Jan. 27, 1992; 57 FR 39827, Sept. 1, 1992; 57 FR 46510, Oct. 9, 1992; 59 FR 45399, Sept. 1, 1994; 61 FR 46224, Aug. 30, 1996; 61 FR 51217, Oct. 1, 1996]

§ 412.304 Implementation of the capital prospective payment system.

(a) *General rule*. As described in §§ 412.312 through 412.370, effective with cost reporting periods beginning on or after October 1, 1991, CMS pays an amount determined under the capital prospective payment system for each inpatient hospital discharge as defined in § 412.4. This amount is in addition to the amount payable under the prospective payment system for inpatient hospital operating costs as determined under subpart D of this part.

(b) *Cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001*. For cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001, the capital payment amount is based on either a combination of payments for old capital costs and new capital costs or a fully prospective rate, as determined under § 412.324 through § 412.348.

(c) *Cost reporting periods beginning on or after October 1, 2001*—(1) *General*. Except as provided in paragraph (c)(2) of this section, for cost reporting periods beginning on or after October 1, 2001, the capital payment amount is based solely on the Federal rate determined under §§ 412.308(a) and (b) and updated under § 412.308(c).

(2) *Payment to new hospitals*. For cost reporting periods beginning on or after October 1, 2002—

(i) A new hospital, as defined under § 412.300(b), is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its cost report ending at least 2 years after the hospital accepts its first patient, unless the new hospital elects to be paid under the capital prospective payment system based on 100 percent of the Federal rate.

(A) If the new hospital elects to be paid based on 100 percent of the Federal rate, the new hospital must submit a written request to the fiscal intermediary by the later of December 1, 2002 or 60 days before the beginning of its cost reporting period.

(B) Once a new hospital elects to be paid based on 100 percent of the Federal rate, it may not revert to payment at 85 percent of its allowable Medicare inpatient hospital capital-related costs.

(ii) For the third year and subsequent years, the hospital is paid based on the Federal rate as described under § 412.312.

(d) *Interim payments*. Interim payments are made to the hospital as provided in § 412.116.

[56 FR 43449, Aug. 30, 1991, as amended at 67 FR 50113, Aug. 1, 2002; 70 FR 47487, Aug. 12, 2005]

BASIC METHODOLOGY FOR DETERMINING THE FEDERAL RATE FOR CAPITAL-RELATED COSTS

§ 412.308 Determining and updating the Federal rate.

(a) *FY 1992 national average cost per discharge*. CMS determines the FY 1992 estimated national average cost per discharge by updating the discharge weighted national average Medicare inpatient hospital capital-related cost per discharge for FY 1989 by the estimated increase in Medicare inpatient hospital capital costs per discharge.

(b) *Standard Federal rate*. The standard Federal rate is used to determine the Federal rate for each fiscal year in accordance with the formula specified in paragraph (c) of this section.

(1) CMS determines the standard Federal rate by adjusting the FY 1992 updated national average cost per discharge by a factor so that estimated aggregate payments based on the standard Federal rate adjusted by the payment adjustments described in § 412.312(b) equal estimated aggregate payments based solely on the national average cost per discharge.

(2) Effective FY 1994, the standard Federal rate used to determine the Federal rate each year under paragraph (c) of this section is reduced by 7.4 percent.

(3) Effective FY 1996, the standard Federal rate used to determine the Federal rate each year under paragraph (c) of this section is reduced by 0.28

percent to account for the effect of the revised policy for payment of transfers under § 412.4(d).

(4) Effective FY 1998, the unadjusted standard Federal capital payment rate in effect on September 30, 1997, used to determine the Federal rate each year under paragraph (c) of this section is reduced by 15.68 percent.

(5) For discharges occurring on or after October 1, 1997 through September 30, 2002, the unadjusted standard Federal capital payment rate as in effect on September 30, 1997, used to determine the Federal rate each year under paragraph (c) of this section is further reduced by 2.1 percent.

(6) For discharges occurring on or after October 1, 2002, the 2.1 percent reduction provided for under paragraph (b)(5) of this section is eliminated from the unadjusted standard Federal rate in effect on September 30, 2002, used to determine the Federal rate each year under paragraph (c) of this section.

(c) *The Federal rate.* CMS determines the Federal rate each year by adjusting the standard Federal rate by the following factors.

(1) *Update factor.* After FY 1992, CMS updates the standard Federal rate as follows:

(i) *FY 1993 through FY 1995.* For FY 1993 through FY 1995, the standard Federal rate is updated based on a moving two-year average of actual increases in capital-related costs per discharge for the period three and four years before the fiscal year in question, excluding the portion of the increase attributable to changes in case mix.

(ii) *Effective FY 1996.* Effective FY 1996, the standard Federal rate is updated based on an analytical framework. The framework includes a capital input price index, which measures the annual change in the prices associated with capital-related costs during the year. CMS adjusts the capital input price index rate of change to take into account forecast errors, changes in the case mix index, the effect of changes to DRG classification and relative weights, and allowable changes in the intensity of hospital services.

(2) *Outlier payment adjustment factor.* CMS reduces the updated standard Federal rate by an adjustment factor equal to the estimated additional payments under the Federal rate for outlier cases under subpart F of this part, determined as a proportion of total capital payments under the Federal rate.

(3) *Exceptions payment adjustment factor.* CMS reduces the updated standard Federal rate by an adjustment factor equal to the estimated additional payments for exceptions under § 412.348 determined as a proportion of total payments under the hospital-specific rate and Federal rate.

(4) *Budget neutrality adjustment factor.* (i) For FY 1992 through FY 1995, CMS adjusts the updated standard Federal rate by a budget neutrality factor determined under § 412.352.

(ii) CMS makes an adjustment to the Federal rate so that estimated aggregate payments for the fiscal year based on the Federal rate after any changes resulting from the annual reclassification and recalibration of the DRG weight in accordance with § 412.60(e) and in the geographic adjustment factors described in § 412.312(b)(2) equal estimated aggregate payments based on the Federal rate that would have been made without such changes.

[56 FR 43449, Aug. 30, 1991; 57 FR 3016, Jan. 27, 1992, as amended at 58 FR 46339, Sept. 1, 1993; 59 FR 45399, Sept. 1, 1994; 60 FR 45849, Sept. 1, 1995; 62 FR 46031, Aug. 29, 1997; 67 FR 50113, Aug. 1, 2002]

§ 412.312 Payment based on the Federal rate.

(a) *General.* The payment amount for each discharge based on the Federal rate determined under § 412.308(c) is determined under the following formula: [Federal rate×DRG weight×Geographic adjustment factor×Large urban add-on×(1+Capital disproportionate share adjustment factor + capital indirect medical education adjustment factor)×(for hospitals located in Alaska and Hawaii, a cost-of-living adjustment factor)]+(Any applicable outlier payment).

(b) *Payment adjustments*—(1) *DRG weights.* The relative resource requirements of the discharge are taken into account by applying the DRG weighting factor that is assigned to the discharge under § 412.60.

(2) *Geographic adjustment factors*—(i) *Local cost variation.* A geographic adjustment factor is applied that takes

into account geographic variation in costs.

(ii) *Large urban add-on*. An additional adjustment is made for hospitals located in a large urban area to reflect the higher costs incurred by hospitals located in those areas. For purposes of the payment adjustment under this paragraph, the definition of large urban area set forth at §412.63(c)(6) continues to be in effect for discharges occurring on or after September 30, 2004.

(iii) *Cost-of-living adjustment*. An additional adjustment is made for hospitals located in Alaska and Hawaii to account for the higher cost-of-living in those States.

(3) *Disproportionate share adjustment*. For hospitals with at least 100 beds located in an urban area and serving low-income patients, a disproportionate share adjustment factor is applied that reflects the higher costs attributable to furnishing services to low income patients.

(4) *Indirect medical education adjustment*. An additional adjustment is made based on the ratio of residents to the average daily patient census of the hospital to account for the indirect costs of medical education.

(c) *Additional payment for outlier cases*. Payment is made for day outlier cases as provided for in §412.82 and for cost outlier cases if both capital-related and operating-related costs exceed the cost outlier threshold as provided for in §412.84.

(d) *Payment for transfer cases*. Payment is made for transfer cases as provided for in §412.4.

(e) *Payment for extraordinary circumstances*. For cost reporting periods beginning on or after October 1, 2001—

(1) Payment for extraordinary circumstances is made as provided for in §412.348(f).

(2) Although no longer independently in effect, the minimum payment levels established under §412.348(c) continue to be used in the calculation of exception payments for extraordinary circumstances, according to the formula in §412.348(f).

(3) Although no longer independently in effect, the offsetting amounts established under §412.348(e) continue to be used in the calculation of exception payments for extraordinary circumstances. However, for cost reporting periods beginning during FY 2005 and subsequent fiscal years, the offsetting amounts in §412.348(e) are determined based on the lesser of—

(i) The preceding 10-year period; or

(ii) The period of time under which the hospital is subject to the prospective payment system for capital-related costs.

[56 FR 43449, Aug. 30, 1991, as amended at 67 FR 50113, Aug. 1, 2002; 69 FR 49250, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

§412.316 Geographic adjustment factors.

(a) *Local cost variation*. CMS adjusts for local cost variation based on the hospital wage index value that is applicable to the hospital under §412.63(k). The adjustment factor equals the hospital wage index value applicable to the hospital raised to the .6848 power and is applied to 100 percent of the Federal rate.

(b) *Large urban location*. CMS provides an additional payment to a hospital located in a large urban area equal to 3.0 percent of what would otherwise be payable to the hospital based on the Federal rate.

(1) For discharges occurring on or before September 30, 2004, the payment adjustment under this section is based on a hospital's location for the purpose of receiving payment under §412.63(a). The term ''large urban area'' is defined under §412.63(c)(6).

(2) For discharges occurring on or after October 1, 2004, the definition of large urban area under §412.63(c)(6) continues to be in effect for purposes of the payment adjustment under this section, based on the geographic classification under §412.64.

(c) *Cost-of-living adjustment*. CMS provides an additional payment to a hospital located in Alaska and Hawaii equal to [.3152×(the cost-of-living adjustment factor used to determine payments under §412.115−1)] percent.

[56 FR 43449, Aug. 30, 1991, Aug. 11, 2004, as amended at 69 FR 49250, Aug. 11, 2004]

§ 412.320 Disproportionate share adjustment factor.

(a) *Criteria for classification.* A hospital is classified as a ''disproportionate share hospital'' for the purposes of capital prospective payments if either of the following conditions is met:

(1) The hospital is located in an urban area, has 100 or more beds as determined in accordance with § 412.105(b), and serves low-income patients as determined under § 412.106(b).

(i) For discharges occurring on or before September 30, 2004, the payment adjustment under this section is based on a hospital's location, for the purpose of receiving payment, under § 412.63(a).

(ii) For discharges occurring on or after October 1, 2004, the payment adjustment under this section is based on the geographic classifications specified under § 412.64.

(2) The hospital meets the criteria in § 412.106(c)(2).

(b) *Payment adjustment factor.* (1) If a hospital meets the criteria in paragraph (a)(1) of this section for a disproportionate share hospital for purposes of capital prospective payments, the disproportionate share payment adjustment factor equals [e raised to the power of (.2025×the hospital's disproportionate patient percentage as determined under § 412.106(b)(5)), −1], where e is the natural antilog of 1.

(2) If a hospital meets the criteria in § 412.106(c)(2) for purposes of hospital inpatient operating prospective payments, the disproportionate share adjustment factor is the factor that results from deeming the hospital to have the same disproportionate share patient percentage that would yield its operating disproportionate share adjustment.

[56 FR 43449, Aug. 30, 1991; 57 FR 3016, Jan. 27, 1992, as amended at 58 FR 46339, Sept. 1, 1993; 69 FR 49250, Aug. 11, 2004]

§ 412.322 Indirect medical education adjustment factor.

(a) *Basic data.* CMS determines the following for each hospital:

(1) The hospital's number of full-time equivalent residents as determined under § 412.105(f).

(2) The hospital's average daily census is determined by dividing the total number of inpatient days in the acute inpatient area of the hospital by the number of days in the cost reporting period.

(3) The measurement of teaching activity is the ratio of the hospital's full-time equivalent residents to average daily census. This ratio cannot exceed 1.5.

(b) *Payment adjustment factor.* The indirect teaching adjustment factor equals [e (raised to the power of .2822×the ratio of residents to average daily census) − 1].

[56 FR 43449, Aug. 30, 1991, as amended at 63 FR 26357, May 12, 1998; 63 FR 41004, July 31, 1998]

DETERMINATION OF TRANSITION PERIOD PAYMENT RATES FOR CAPITAL-RELATED COSTS

§ 412.324 General description.

(a) *Hospitals under Medicare in FY 1991.* During the ten-year transition period, payments to a hospital with a hospital-specific rate below the Federal rate are based on the fully prospective payment methodology under § 412.340 or for a hospital with a hospital-specific rate above the Federal rate, the hold-harmless payment methodology under § 412.344.

(b) *New hospitals.* (1) A new hospital, as defined under § 412.300(b), is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its cost reporting period ending at least 2 years after the hospital accepts its first patient.

(2) For the third year through the remainder of the transition period, the hospital is paid based on the fully prospective payment methodology or the hold-harmless payment methodology using the base period determined under § 412.328(a)(2).

(3) If the hospital is paid under the hold-harmless methodology described in § 412.344, the hold-harmless payment for old capital costs described in § 412.344(a)(1) is payable for up to and including 8 years and may continue beyond the first cost reporting period beginning on or after October 1, 2000.

(c) *Hospitals with 52–53 week fiscal years ending September 25 through September 29.* For purposes of this subpart, a hospital with a 52–53 week fiscal year period beginning September 26 through September 30, 1992 is deemed to have the same beginning date for all cost reporting periods beginning before October 1, 2000 (unless the hospital later changes its cost reporting period).

[56 FR 43449, Aug. 30, 1991; 57 FR 3016, Jan. 27, 1992]

§412.328 Determining and updating the hospital-specific rate.

(a) *Base-year cost reporting period.* (1) *Last 12 month cost reporting period ending on or before December 31, 1990.* For each hospital, the intermediary uses the hospital's latest 12-month or longer cost reporting period ending on or before December 31, 1990 as the base period to determine a hospital's hospital-specific rate.

(2) *New hospitals.* The base-year cost reporting period for a new hospital is its 12-month cost reporting period (or a combination of cost reporting periods covering at least 12 months) that begins at least 1 year after the hospital accepts its first patient.

(3) *Other hospitals.* For other than a new hospital as defined in §412.300(b), if a hospital does not have a 12-month cost reporting period or does not have adequate Medicare utilization to file a cost report in a period ending on or before December 31, 1990, the hospital-specific rate is based on the hospital's old capital costs (per discharge) in its first 12-month cost reporting period (or combination of cost reporting periods covering at least 12 months) ending after December 31, 1990.

(b) *Base-year costs per discharge.* (1) *Base period allowable inpatient capital costs per discharge.* (i) *Determination.* The intermediary determines the base period allowable inpatient capital costs per discharge for the hospital by dividing the hospital's total allowable Medicare inpatient hospital capital-related cost in the base period by the number of Medicare discharges in the base period.

(ii) *Disposal of assets in the base year.* When a depreciable asset has been disposed of in the base year, only that portion of the gain or loss that is allocated to the base-year cost reporting period is reflected in the hospital-specific rate.

(iii) *Disposal of assets subsequent to the base year.* If an asset for which the Medicare program had recognized depreciation during the base year is disposed of subsequent to the base year, the hospital-specific rate will not be revised to recognize the portion of the gain or loss allocated to the base year.

(2) *Discharges.* For the purpose of determining a hospital's base period capital costs per discharge, a discharge includes discharges as defined in §412.4(a) and transfers as defined in §412.4(b)(2), adjusted by the transfer adjustment factor that is determined under paragraph (b)(3) of this section.

(3) *Transfer adjustment factor.* (i) For base year cost reporting periods ending on or before December 31, 1990, CMS uses the base year MEDPAR data received as of June 30, 1991 to develop an adjustment to discharges to account for transfers. CMS divides the length of stay for each transfer case by the geometric mean length of stay for the DRG (but in no case using a number greater than 1.0) and assigns each non-transfer case a value of 1.0. To determine the transfer adjustment factor, CMS adds together the adjusted discharges and divides the result by total discharges including transfers.

(ii) For base year cost reporting periods ending after December 31, 1990 but beginning before October 1, 1991, CMS determines a transfer adjustment factor as described in paragraph (b)(3)(i) of this section for a hospital using the applicable base year MEDPAR data on file as of the December 31 or June 30 occurring at least 6 months after the close of the approved base year.

(iii) For base year cost reporting periods beginning on or after October 1, 1991, the intermediary determines the transfer adjustment factor in place of CMS as described in paragraph (b)(3)(i) of this section based on the most recent billing data available as of the date of the final determination of the hospital-specific rate.

(c) *Case-mix adjustment.* (1) *Determining transfer-adjusted case mix value. Step 1:* For base year cost reporting periods ending on or before December 31, 1990, CMS uses the base year MEDPAR

data received as of June 30, 1991 to determine the hospital's transfer-adjusted case-mix value. For base year cost reporting periods ending after December 31, 1990 and beginning before October 1, 1991, CMS determines a transfer-adjusted case-mix value for a hospital using the applicable base year MEDPAR data on file as of the December 31 or June 30 occurring at least 6 months after the close of the base year. For base year cost reporting periods beginning on or after October 1, 1991, the intermediary determines the transfer-adjusted case-mix value based on the most recent billing data available as of the date of the final determination of the hospital-specific rate. CMS or the intermediary, as appropriate, multiplies the DRG weight for each case by one of the following factors:

(i) If the case is not a transfer, the factor equals 1.0.

(ii) If the case is a transfer, the factor equals the lesser of 1.0 or the ratio of the length of stay for the case divided by the geometric mean length of stay for the DRG.

Step 2: The products derived for all cases under Step 1 are added together and the result is divided by the adjusted discharges used to calculate the transfer adjustment factor determined under paragraph (b)(3) of this section.

(2) *Adjusting base period capital costs per discharge by the hospital's transfer-adjusted case-mix value.* The intermediary divides the base period capital costs per discharge for each hospital as determined in paragraph (b) of this section by the hospital's transfer-adjusted case mix value for the cost reporting period determined under paragraph (c)(1) of this section.

(d) *Updatinq to FY 1992.* The intermediary updates the case-mix adjusted base period costs per discharge to FY 1992 based on the national average increase in Medicare inpatient capital costs per discharge as estimated by CMS, excluding the portion of the increase in capital costs per discharge attributable to changes in case mix.

(e) *Hospital-specific rate.* The intermediary determines the hospital-specific rate each year by adjusting the amount determined under paragraph (d) of this section by the following factors:

(1) *Update factor.* After FY 1992, the intermediary updates the hospital-specific rate in accordance with § 412.308(c)(1).

(2) *Exceptions payment adjustment factor.* For FY 1992 through FY 2001, the intermediary reduces the updated amount determined in paragraph (d) of this section by an adjustment factor equal to the estimated additional payments for capital-related costs for exceptions under § 412.348, determined as a proportion of the total amount of payments under the hospital-specific rate and Federal rate.

(3) *Budget neutrality adjustment factor.* For FY 1992 through FY 1995, the intermediary adjusts the updated amount determined in paragraph (d) of this section by a budget neutrality adjustment factor determined under § 412.352.

(4) *Payment for transfer cases.* Effective FY 1996, the intermediary reduces the updated amount determined in paragraph (d) of this section by 0.28 percent to account for the effect of the revised policy for payment of transfers under § 412.4(d).

(5) *Reduction of rate: FY 1998.* Effective FY 1998, the unadjusted hospital-specific rate as in effect on September 30, 1997 described in paragraph (e)(1) of this section is reduced by 15.68 percent.

(6) *Reduction of rate: FY 1998 through FY 2002.* For discharges occurring on or after October 1, 1997 through September 30, 2002, the unadjusted hospital-specific rate in effect on September 30, 1997, described in paragraph (e)(1) of this section is further reduced by 2.1 percent.

(f) *Redetermination of hospital-specific rate.* (1) *General.* (i) Upon request by a hospital, the intermediary redetermines the hospital-specific rate to reflect an increase in old capital costs as determined in a cost reporting period subsequent to the base year. An increase in Medicare old capital cost per discharge that is related solely to a decline in utilization is not recognized as an increase in old capital costs for purposes of this section. New capital costs are excluded from the redetermination of the hospital-specific rate.

(ii) The hospital may request redetermination for any cost reporting period beginning subsequent to the base period but no later than the later of the

hospital's cost reporting period beginning in FY 1994 or the cost reporting period beginning after obligated capital that is recognized as old capital under §412.302(b) is put in use.

(iii) The hospital must request a redetermination in writing no later than the date the cost report must be filed with the hospital's intermediary for the first cost reporting period beginning on or after October 1, 1991 or the cost reporting period that will serve as the new base period, whichever is later. The hospital's redetermination request must include the cost report for the new base period and an estimate of the revised hospital-specific rate indicating that the new rate exceeds the hospital's current hospital-specific rate.

(2) *Determination of old capital costs.* The intermediary determines the hospital's old capital costs for the subsequent cost reporting period that will serve as the new base period. The intermediary includes the costs of obligated capital that are recognized as old capital costs under §412.302(b), excludes the costs of assets disposed of subsequent to the initial base year, and reflects changes in allowable old capital costs occurring subsequent to the initial base period.

(3) *Redetermined hospital-specific rate.* The intermediary redetermines the hospital-specific rate based on the old capital costs that are determined under paragraph (f)(2) of this section for the new base period. The intermediary—

(i) Divides the hospital's old capital costs for the new base period by the number of Medicare discharges in that cost reporting period (consistent with paragraph (b) of this section);

(ii) Divides the old capital costs per discharge by the hospital's transfer adjusted case-mix value for the new base period (consistent with paragraph (c) of this section);

(iii) Applies an update factor, if appropriate, to account for inflation occurring subsequent to the new base year, an exceptions payment adjustment factor, and a budget neutrality adjustment factor (consistent with paragraphs (d) and (e) of this section).

(4) *Denial by intermediary.* If the intermediary determines, after audit, that the revised hospital-specific rate is lower than the current hospital-specific rate, it advises the hospital that its request is denied and explains the basis for the denial.

(5) *Implementation date.* The redetermined hospital-specific rate applies to discharges occurring on or after the beginning date of the new base period.

(g) *Review and revision of the hospital-specific rate.* (1) *Interim determination.* The intermediary makes an interim determination of the hospital-specific rate based on the best data available and notifies the hospital at least 30 days before the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991.

(2) *Final determination.* (i) The intermediary makes a final determination of the hospital-specific rate based on the final settlement of the base period cost report.

(ii) The final determination of the hospital-specific rate is effective retroactively to the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991 or, in the case of a redetermination of the hospital-specific rate under §412.328(f), to the beginning of the new base period.

(iii) The final determination of the hospital-specific rate is subject to administrative and judicial review in accordance with subpart R of part 405 of this chapter, governing provider reimbursement determinations and appeals.

(iv) The intermediary adjusts the hospital-specific rate to reflect any revisions that result from administrative or judicial review of the final determination of hospital-specific rate. The revised determination is effective retroactively to the same extent as in paragraph (g)(2)(ii) of this section.

[56 FR 43449, Aug. 30, 1991; 57 FR 3016, 3017, Jan. 27, 1992; 57 FR 39828, Sept. 1, 1992; 60 FR 45849, Sept. 1, 1995; 62 FR 46031, Aug. 29, 1997]

§412.331 Determining hospital-specific rates in cases of hospital merger, consolidation, or dissolution.

(a) *New hospital merger or consolidation.* If, after a new hospital accepts its first patient but before the end of its base year, it merges with one or more existing hospitals, and two or more separately located hospital campuses are maintained, the hospital-specific

rate and payment determination for the merged entity are determined as follows—

(1) *Post-merger base year payment methodology*. The new campus is paid based on reasonable costs until the end of its base year. The existing campus remains on its previous payment methodology until the end of the new campus' base year. Effective with the first cost reporting period beginning after the end of the new campus' base year, the intermediary determines a hospital-specific rate applicable to the new campus in accordance with § 412.328, and then determines a revised hospital-specific rate for the merged entity in accordance with paragraph (a)(2) of this section.

(2) *Revised hospital-specific rate*. Using each hospital's base period data, the intermediary determines a combined average discharge-weighted hospital-specific rate.

(3) *Post-base year payment determination*. To determine the applicable payment methodology under § 412.336 and for payment purposes under § 412.340 or § 412.344, the discharge-weighted hospital-specific rate determined by the intermediary is compared to the Federal rate. The revised payment methodology is effective on the first day of the cost reporting period beginning after the end of the new campus' base year.

(b) *Hospital merger or consolidation*. If, after the base year, two or more hospitals merge or consolidate into one hospital as provided for under § 413.134(k) of this chapter and the provisions of paragraph (a) of this section do not apply, the intermediary determines a revised hospital-specific rate applicable to the combined facility under § 412.328, which is effective beginning with the date of merger or consolidation. The following rules apply to the revised hospital-specific rate and payment determination:

(1) *Revised hospital-specific rate*. Using each hospital's base period data, the intermediary determines a combined average discharge weighted hospital-specific rate.

(2) *Payment determination*. The discharge-weighted hospital-specific rate determined by the intermediary is compared to the Federal rate to establish the appropriate payment methodology under § 412.336 and for payment purposes under §§ 412.340 or 412.344. The revised payment methodology is effective as of the date of merger or consolidation.

(3) *Old capital cost determination*. The capital-related costs related to the assets of each merged or consolidated hospital as of December 31, 1990 are recognized as old capital costs during the transition period. If the hospital is paid under the hold-harmless methodology after merger or consolidation, only that original base year old capital is eligible for hold-harmless payments.

(c) *Hospital dissolution*. If a hospital separates into two or more hospitals that are subject to capital payments under this subpart after the base year, the intermediary determines new hospital-specific rates for each separate hospital under the provisions of § 412.328 effective as of the date of the dissolution. The new hospital-specific rates are determined as follows:

(1) *Hospital-specific rate*—(i) *Adequate base year data*. The intermediary determines whether the base year capital-related cost data and necessary statistical records are adequate to reconstruct the cost and other data required under § 412.328 from the former hospital's financial records to determine the hospital-specific rates for each facility. If the data are adequate, the intermediary uses the former hospital's base period to determine the hospital-specific rate for each separate hospital.

(ii) *Inadequate original base year data*. If the intermediary determines that the base period data for the former hospital is inadequate to establish separate hospital-specific rates, the intermediary establishes a new base period for each hospital. The new base period is each hospital's first 12-month or longer cost reporting period (or combination of cost reporting periods covering at least 12 months) immediately following separation of the hospitals. The intermediary determines the hospital-specific rate for each hospital using the new base period under § 412.328.

(2) *Payment determinations*. The intermediary applies the payment methodology provisions of §412.336. The revised payment determination is effective as of the date of the hospital's dissolution.

(3) *Old capital cost determination*. In determining the old capital costs for each hospital, the amount recognized as old capital is limited to the allowable capital-related costs attributable to assets that were in use for patient care as of December 31, 1990, and the hospitals are subject to all other transition period rules of this subpart.

[57 FR 39828, Sept. 1, 1992, as amended at 63 FR 41004, July 31, 1998]

§412.332 Payment based on the hospital-specific rate.

The payment amount for each discharge (as defined in §412.4(a)) based on the hospital-specific rate determined under §412.328 (e) or (f) is determined by multiplying the applicable hospital-specific rate by the DRG weighting factor applicable to the discharge under §412.60 and the applicable hospital-specific rate percentage for the pertinent cost reporting period under §412.340.

§412.336 Transition period payment methodologies.

(a) *General*. For discharges occurring in cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001, a hospital is paid under one of two payment methodologies described in §412.340 and §412.344. Except as provided under paragraph (b) of this section, a hospital is paid under the same methodology throughout the transition period.

(1) *Hospital-specific rate below the Federal rate*. A hospital with a hospital-specific rate below the Federal rate (after taking into account the estimated effect of the payment adjustments and outlier payments) is paid under the fully prospective payment methodology as described in §412.340.

(2) *Hospital-specific rate above the Federal rate*. A hospital with a hospital-specific rate that is above the Federal rate (after taking into account the estimated effect of the payment adjustments and outlier payments) is paid under the hold-harmless payment methodology as described in §412.344.

(b) *Special rule for revised hospital-specific rate*. If a hospital with a hospital-specific rate below the Federal rate requests that its hospital-specific rate be redetermined, the redetermined hospital-specific rate is compared to the Federal rate that is applicable to the new base period (after taking into account the estimated effect of the payment adjustments and outlier payments). If the redetermined hospital-specific rate is higher than the Federal rate, the hospital is paid under the hold-harmless methodology effective with the beginning of the new base period and continuing throughout the remainder of the transition.

(c) *Interim and final determinations of applicable payment methodology*—(1) *Interim determination*. The intermediary makes an interim determination of the applicable payment methodology based on the best data available and notifies the hospital of its determination at least 30 days before the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991.

(2) *Final determination*. (i) The intermediary makes a final determination of the applicable payment methodology based on its final determination of the hospital's hospital-specific rate. The final determination of the applicable payment methodology is effective retroactively to the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991.

(ii) If the hospital-specific rate is redetermined in accordance with §412.328(f), the intermediary makes a new determination of the applicable payment methodology. The new determination is effective retroactively to the beginning of the new base period.

(iii) If the hospital-specific rate is revised under §412.328(g) as a result of administrative or judicial review, the intermediary makes a new determination of the applicable payment methodology. The new determination is effective retroactively to the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991 or to the beginning of the new base period.

(d) *Special Rule for Redetermination of Hospital Payment Methodology*. For cost reporting periods beginning on or after

October 1, 1993, the intermediary redetermines the hospital payment methodologies to take into account the reduction to the standard Federal rate provided in § 412.308(b)(2):

(1) For a hospital paid under the fully prospective payment methodology in the last hospital cost reporting period beginning before October 1, 1993, the intermediary compares the hospital's FY 1994 hospital-specific rate with the hospital's FY 1994 Federal rate (after taking into account the estimated effect of the payment adjustments and outlier payments).

(i) A hospital with a FY 1994 hospital-specific rate that is above the FY 1994 adjusted Federal rate is paid under the hold-harmless payment methodology described in § 412.344.

(ii) Subject to the provisions of § 412.328(f), a hospital with a FY 1994 hospital-specific rate that is below the FY 1994 adjusted Federal rate continues to be paid under the fully prospective payment methodology as described in § 412.340.

(iii) The intermediary notifies the hospital of the new determination of the hospital's payment methodology within 90 days of the hospital's first cost reporting period beginning on or after October 1, 1993. The new determination is effective to the beginning of the hospital's first cost reporting period beginning on or after October 1, 1993.

(2) A hospital paid under the hold-harmless payment methodology in the last cost reporting period beginning before October 1, 1993, will continue to be paid in accordance with the provisions of § 412.344.

[56 FR 43449, Aug. 30, 1991; 57 FR 3017, Jan. 27, 1992, as amended at 58 FR 46340, Sept. 1, 1993]

§ 412.340 Fully prospective payment methodology.

A hospital paid under the fully prospective payment methodology receives a payment per discharge based on a proportion of the hospital-specific rate and the Federal rate as follows:

Cost reporting periods beginning on or after:	Federal rate percentage	Hospital-specific rate percentage
October 1, 1991	10	90
October 1, 1992	20	80
October 1, 1993	30	70
October 1, 1994	40	60
October 1, 1995	50	50
October 1, 1996	60	40
October 1, 1997	70	30
October 1, 1998	80	20
October 1, 1999	90	10
October 1, 2000	100	0

§ 412.344 Hold-harmless payment methodology.

(a) *General.* A hospital paid under the hold-harmless payment methodology receives a payment per discharge based on the higher of:

(1) 85 percent of reasonable costs for old capital costs (100 percent for sole community hospitals) plus an amount for new capital costs based on a proportion of the Federal rate. The proportion is equal to the ratio of the hospital's Medicare inpatient costs for new capital to total Medicare inpatient capital costs; or

(2) 100 percent of the Federal rate.

(3) *Exceptions.* (i) A hospital that would receive higher payment under paragraph (a)(1) of this section may elect payment based on 100 percent of the Federal rate under paragraph (a)(2) of this section.

(ii) A hospital that does not maintain records that are adequate to identify its old capital costs is deemed to have elected payment per discharge based on 100 percent of the Federal rate.

(b) *Continued basis of payment.* A hospital paid based on 100 percent of the Federal rate during the later of its cost reporting period beginning in FY 1994 or its first cost reporting period beginning after obligated capital that is recognized as old capital under § 412.302(b) is put in use continues to be paid on that basis in subsequent cost reporting periods during the transition period and does not receive a reasonable cost payment for old capital costs under paragraph (a)(1) of this section.

(c) *Basis of determination.* The determination under paragraph (a) of this section regarding which payment alternative is applicable is made without regard to additional payments under the exceptions process under § 412.348.

(d) *Interim and final payment determinations.* (1) Using the best data available, the intermediary makes an interim payment determination under paragraph (a) of this section concerning the applicable payment alternative, and, in the case of payment under paragraph (a)(1) of this section, the payment amounts for old and new capital. The intermediary notifies the hospital of its determination at least 30 days before the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991. The intermediary may revise its determination based on additional information submitted by the hospital and make appropriate adjustments retroactively.

(2) The final determination of the amount payable under paragraph (a) of this section is based on final settlement of the Medicare cost report for the applicable cost reporting period and is effective retroactively to the beginning of that cost reporting period. This final determination is subject to administrative and judicial review in accordance with subpart R of part 405 of this chapter, governing provider reimbursement determinations and appeals.

[56 FR 43449, Aug. 30, 1991; 57 FR 3017, Jan. 27, 1992]

§412.348 Exception payments.

(a) *Definitions.* As used in this section—

Annual operating expenses. Annual operating expenses means the sum of net expenses for all reimbursable cost centers for a 12 month cost reporting period. Annual operating expenses are obtained from the Medicare cost report.

Average age of fixed assets. The average age of fixed assets is the ratio of accumulated depreciation for buildings and fixed equipment to current depreciation expense for buildings and fixed equipment. The average age of fixed assets is determined from information on the Medicare cost report.

Fixed assets. Fixed assets mean buildings and fixed equipment.

(b) *Criterion for additional payment during the transition period.* An additional payment is made to a hospital paid under either the fully prospective payment methodology or the hold-harmless payment methodology as determined under paragraph (c) of this section for cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001.

(c) *Minimum payment level by class of hospital.* (1) CMS establishes a minimum payment level by class of hospital. The minimum payment level for a hospital will equal a fixed percentage of the hospital's capital-related costs. The minimum payment levels may be no greater than the percentages of allowable capital-related costs that follow:

(i) 90 percent for sole community hospitals.

(ii) 80 percent for hospitals located in an urban area for purposes of §412.63(a) with at least 100 beds, as determined under §412.105(b), that have a disproportionate share patient percentage of at least 20.2 percent as determined under §412.106(b), and for hospitals located in an urban area for purposes of §412.63(a) with at least 100 beds that qualify for disproportionate share payments under §412.106(c)(2).

(iii) 70 percent for all other hospitals.

(2) When it is necessary to adjust the minimum payment levels set by class of hospitals specified in paragraphs (c)(1)(i) and (g)(6) of this section, CMS will adjust those levels for each class of hospitals in one percentage point increments as necessary to satisfy the requirement specified in paragraph (h) of this section that total estimated payments under the exception process not exceed 10 percent of the total estimated capital prospective payments (exclusive of hold-harmless payments for old capital) for the same fiscal year.

(d) *Additional payments.* A hospital is entitled to an additional payment if its capital payments for the cost reporting period would otherwise be less than the applicable minimum payment level. The additional payment equals the difference between the applicable minimum payment level and the capital payments that the hospital would otherwise receive minus any offset amount determined under paragraph (e)(2) of this section.

(e) *Determining a hospital's exception payment amount*—(1) *Cumulative comparison.* For each cost reporting period beginning before October 1, 2001, the

hospital's exception payment is determined by comparing the cumulative payments made to the hospital under the capital prospective payment system to the cumulative minimum payment levels applicable to the hospital for each cost reporting period subject to the prospective payment system.

(2) *Offsetting amounts.* Any amount by which the hospital's cumulative payments exceed its cumulative minimum payment levels is deducted from the additional payment that would otherwise be payable for a cost reporting period.

(f) *Additional payment exception for extraordinary circumstances.* (1) A hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million (net of proceeds from other payment sources such as insurance, litigation decisions and other State, local or Federal government funding programs) due to extraordinary circumstances beyond the hospital's control. Extraordinary circumstances include, but are not limited to, a flood, fire, or earthquake.

(2) A hospital must apply to its CMS Regional Office by the later of October 1, 1992 or 180 days after the extraordinary circumstance causing the unanticipated expenditures for a determination by CMS of whether the hospital is eligible for an additional payment based on the nature of the circumstances and the amount of financial loss documented by the hospital.

(3) Except for sole community hospitals, the additional payment is based on a minimum payment amount of 85 percent for Medicare's share of allowable capital-related costs attributable to the extraordinary circumstances. For sole community hospitals, the minimum payment amount is 100 percent.

(4) The minimum payment level applicable under paragraph (c)(1) of this section is adjusted to take into account the 85 percent minimum payment level (100 percent for sole community hospitals) under paragraph (f)(3) of this section for the unanticipated capital-related costs. The additional payment for the cost reporting period equals the difference between the adjusted minimum payment level and the capital payments the hospital would otherwise receive less any offset amount determined under paragraph (e)(2) of this section.

(g) *Special exceptions process.* For eligible hospitals that meet a project need requirement, a project size requirement, and, in the case of certain urban hospitals, meet an excess capacity test, an additional payment may be made for up to 10 years beyond the end of the capital prospective payment system transition period.

(1) *Eligible hospitals.* The following classes of hospitals are eligible to receive exceptions payments under this special exceptions provision:

(i) Sole community hospitals.

(ii) Hospitals located in an urban area under § 412.63(a) with at least 100 beds, as determined under § 412.105(b), that either have a disproportionate share of at least 20.2 percent as determined under § 412.106(b) or qualify for disproportionate share payments under § 412.106(c)(2).

(iii) Hospitals with a combined inpatient Medicare and Medicaid utilization of at least 70 percent.

(2) *Project need requirement.* A hospital must show that it has obtained any required approval from a State or local planning authority. If a hospital is not required to obtain approval from a planning authority, it must satisfy the age of asset test specified in paragraph (g)(3) of this section and, in the case of an urban hospital, the excess capacity test under paragraph (g)(4) of this section.

(3) *Age of assets test.* A hospital must show that its average age of fixed assets is at or above the 75th percentile for the hospital's first cost reporting period beginning on or after October 1, 1991.

(4) *Excess capacity test for urban hospitals.* Urban hospitals that are not required to receive approval from a State or local planning authority must demonstrate that either—

(i) The overall average occupancy rate in its metropolitan statistical area is at least 80 percent; or

(ii) After completion of the project, its capacity is no more than 80 percent of its prior capacity (in terms of bed size).

(5) *Project size requirement.* A hospital must complete, during the period from

the beginning of its first cost reporting period beginning on or after October 1, 1991 to the end of its last cost reporting period beginning before October 1, 2001, a project whose costs for replacement and/or renovation of fixed assets related to patient care are at least:

(i) $200 million; or

(ii) 100 percent of its operating cost during the first 12 month cost reporting period beginning on or after October 1, 1991.

(6) *Minimum payment level.*

(i) The minimum payment level for qualifying hospitals will be 70 percent.

(ii) CMS will adjust the minimum payment level in one percentage point increments as necessary to satisfy the requirement specified in paragraph (h) of this section that total estimated payments under the exceptions process not exceed 10 percent of the total estimated capital prospective payment system payments for the same fiscal year.

(7) *Limitation on the period for exception payments.* A qualifying hospital may receive an exceptions payment for up to 10 years from the year in which it completes a project for replacement or renovation of capital assets that meets project need and project size requirements (and, if applicable, excess capacity test), provided that it completes the project no later than the end of the hospital's last cost reporting period beginning before October 1, 2001. A project is considered to be completed when the assets are put into use for patient care.

(8) *Determining a hospital's exception payment amount*—(i) *Cumulative comparison.* For each cost reporting period, the hospital's exception payment is determined by comparing the cumulative payments made to the hospital under the capital prospective payment system to the cumulative minimum payment levels applicable to the hospital for each cost reporting period subject to the prospective payment system.

(ii) *Offsetting amounts.* Offsetting amounts are applied in the following order—(A) Any amount by which the hospital's cumulative payments exceed its cumulative minimum payment levels is deducted from the additional payment that would otherwise be payable for a cost reporting period.

(B) Any amount by which the hospital's current year Medicare inpatient operating and capital prospective payment system payments (excluding, if applicable, 75 percent of the hospital's operating prospective payment system disproportionate share payments) exceed its Medicare inpatient operating and capital costs is deducted from the additional payment that would otherwise be payable for the cost reporting period. For purposes of calculating the offset, the costs and payments for services that are not subject to the hospital inpatient prospective payment system are excluded.

(9) *Notification requirement.* Eligible hospitals must submit documentation to the intermediary indicating the completion date of a project that meets the project need requirement under paragraph (g)(2) of this section, the project size requirement under paragraph (g)(5) of this section, and, in the case of certain urban hospitals, an excess capacity test under paragraph (g)(4) of this section, by the later of October 1, 2001 or within 3 months of the end of the hospital's last cost reporting period beginning before October 1, 2001, during which a qualifying project was completed.

(h) *Limit on exception payments.* Total estimated payments under the exception process may not exceed 10 percent of the total estimated capital prospective payments (exclusive of hold-harmless payments for old capital) for the same fiscal year.

[59 FR 45399, Sept. 1, 1994, as amended at 62 FR 46031, Aug. 29. 1997; 66 FR 39936, Aug. 1, 2001]

§412.352 Budget neutrality adjustment.

For FY 1992 through FY 1995, CMS will determine an adjustment to the hospital-specific rate and the Federal rate proportionately so that the estimated aggregate payments under this subpart for inpatient hospital capital costs each fiscal year will equal 90 percent of what CMS estimates would have been paid for capital-related costs on a reasonable cost basis under §413.130 of this chapter.

SPECIAL RULES FOR PUERTO RICO HOSPITALS

§ 412.370 General provisions for hospitals located in Puerto Rico.

Except as provided in § 412.374, hospitals located in Puerto Rico are subject to the rules in this subpart governing the prospective payment system for inpatient hospital capital-related costs.

§ 412.374 Payments to hospitals located in Puerto Rico.

(a) *FY 1998 through FY 2004.* Payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of the following:

(1) 50 percent of the Puerto Rico capital rate based on data from Puerto Rico hospitals only, which is determined in accordance with procedures for developing the Federal rate; and

(2) 50 percent of the Federal rate, as determined under § 412.308.

(b) *FY 2005 and FYs thereafter.* For discharges occurring on or after October 1, 2004, payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of the following:

(1) 25 percent of the Puerto Rico capital rate based on data from Puerto Rico hospitals only, which is determined in accordance with procedures for developing the Federal rate; and

(2) 75 percent of the Federal rate, as determined under § 412.308.

(c) Effective for fiscal year 1998, the Puerto Rico capital rate described in paragraph (a) of this section in effect on September 30, 1997, is reduced by 15.68 percent.

(d) For discharges occurring on or after October 1, 1997 through September 30, 2002, the Puerto Rico capital rate described in paragraph (a) of this section in effect on September 30, 1997 is further reduced by 2.1 percent.

[62 FR 46032, Aug. 29, 1997, as amended at 69 FR 49250, Aug. 11, 2004]

Subpart N—Prospective Payment System for Inpatient Hospital Services of Inpatient Psychiatric Facilities

SOURCE: 69 FR 66977, Nov. 15, 2004, unless otherwise noted.

§ 412.400 Basis and scope of subpart.

(a) *Basis.* This subpart implements section 124 of Public Law 106–113, which provides for the implementation of a per diem-based prospective payment system for inpatient hospital services of inpatient psychiatric facilities.

(b) *Scope.* This subpart sets forth the framework for the prospective payment system for the inpatient hospital services of inpatient psychiatric facilities, including the methodology used for the development of the Federal per diem rate, payment adjustments, implementation issues, and related rules. Under this system, for cost reporting periods beginning on or after January 1, 2005, payment for the operating and capital-related costs of inpatient hospital services furnished by inpatient psychiatric facilities to Medicare Part A fee-for-service beneficiaries is made on the basis of prospectively determined payment amount applied on a per diem basis.

§ 412.402 Definitions.

As used in this subpart—

Comorbidity means all specific patient conditions that are secondary to the patient's primary diagnosis and that coexist at the time of admission, develop subsequently, or that affect the treatment received or the length of stay or both. Diagnoses that relate to an earlier episode of care that have no bearing on the current hospital stay are excluded.

Federal per diem base rate means the payment based on the average routine operating, ancillary, and capital-related cost of 1 day of hospital inpatient services in an inpatient psychiatric facility.

Federal per diem payment amount means the Federal per diem base rate with all applicable adjustments.

Fixed dollar loss threshold means a dollar amount by which the costs of a

case exceed payment in order to qualify for an outlier payment.

Inpatient psychiatric facilities means hospitals that meet the requirements as specified in § 412.22, § 412.23(a), § 482.60, § 482.61, and § 482.62, and units that meet the requirements as specified in § 412.22, § 412.25, and § 412.27.

Interrupted stay means a Medicare inpatient is discharged from an inpatient psychiatric facility and is admitted to any inpatient psychiatric facility within 3 consecutive calendar days following discharge. The 3 consecutive calendar days begins with the day of discharge from the inpatient psychiatric facility and ends on midnight of the third day.

Outlier payment means an additional payment beyond the Federal per diem payment amount for cases with unusually high costs.

Principal diagnosis means the condition established after study to be chiefly responsible for occasioning the admission of the patient to the inpatient psychiatric facility also referred to as primary diagnosis. Principal diagnosis is also referred to as primary diagnosis.

Qualifying emergency department means an emergency department that is staffed and equipped to furnish a comprehensive array of emergency services and meeting the definitions of a dedicated emergency department as specified in § 489.24(b).

Rural area means any area outside an urban area.

Urban area means an area as defined in § 412.62(f)(1)(ii).

[69 FR 66977, Nov. 15, 2004; 70 FR 19728, Apr. 1, 2005]

§ 412.404 Conditions for payment under the prospective payment system for inpatient hospital services of psychiatric facilities.

(a) *General requirements.* (1) Effective for cost reporting periods beginning on or after January 1, 2005, an inpatient psychiatric facility must meet the conditions of this section to receive payment under the prospective payment system described in this subpart for inpatient hospital services furnished in to Medicare Part A fee-for-service beneficiaries.

(2) If an inpatient psychiatric facility fails to comply fully with these conditions, CMS may, as appropriate—

(i) Withhold (in full or in part) or reduce Medicare payment to the inpatient psychiatric facility until the facility provides adequate assurances of compliance; or

(ii) Classify the inpatient psychiatric facility as an inpatient hospital that is subject to the conditions of subpart C of this part and is paid under the prospective payment system as specified in § 412.1(a)(1).

(b) *Inpatient psychiatric facilities subject to the prospective payment system.* Subject to the special payment provisions of § 412.22(c), an inpatient psychiatric facility must meet the general criteria set forth in § 412.22. In order to be excluded from the hospital inpatient prospective payment system as specified in § 412.1(a)(1), a psychiatric hospital must meet the criteria set forth in § 412.23(a), § 482.60, § 482.61, and § 482.62 and psychiatric units must meet the criteria set forth in § 412.25 and § 412.27.

(c) *Limitations on charges to beneficiaries*—(1) *Prohibited charges.* Except as permitted in paragraph (c)(2) of this section, an inpatient psychiatric facility may not charge a beneficiary for any services for which payment is made by Medicare, even if the facility's cost of furnishing services to that beneficiary are greater than the amount the facility is paid under the prospective payment system.

(2) *Permitted charges.* An inpatient psychiatric facility receiving payment under this subpart for a covered hospital stay (that is, a stay that included at least one covered day) may charge the Medicare beneficiary or other person only the applicable deductible and coinsurance amounts under § 409.82, § 409.83, and § 409.87 of this chapter and for items or services as specified under § 489.20(a) of this chapter.

(d) *Furnishing of inpatient hospital services directly or under arrangement.* (1) Subject to the provisions of § 412.422, the applicable payments made under this subpart are payment in full for all inpatient hospital services, as specified in § 409.10 of this chapter. Hospital inpatient services do not include the following:

(i) Physicians' services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(ii) Physician assistant services, as specified in section 1861(s)(2)(K)(i) of the Act.

(iii) Nurse practitioners and clinical nurse specialist services, as specified in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse midwife services, as specified in section 1861(gg) of the Act.

(v) Qualified psychologist services, as specified in section 1861(ii) of the Act.

(vi) Services of a certified registered nurse anesthetist, as specified in section 1861(bb) of the Act and defined in § 410.69 of this subchapter.

(2) CMS does not pay providers or suppliers other than inpatient psychiatric facilities for services furnished to a Medicare beneficiary who is an inpatient of the inpatient psychiatric facility, except for services described in paragraphs (d)(1)(i) through (d)(1)(vi) of this section

(3) The inpatient psychiatric facility must furnish all necessary covered services to a Medicare beneficiary who is an inpatient of the inpatient psychiatric facility, either directly or under arrangements (as specified in § 409.3 of this chapter).

(e) *Reporting and recordkeeping requirements.* All inpatient psychiatric facilities participating in the prospective payment system under this subpart must meet the recordkeeping and cost reporting requirements as specified in § 412.27(c), § 413.20, § 413.24, and § 482.61 of this chapter.

§ 412.422 Basis of payment.

(a) *Method of Payment.* (1) Under the inpatient psychiatric facility prospective payment system, inpatient psychiatric facilities receive a predetermined Federal per diem base rate for inpatient hospital services furnished to Medicare Part A fee-for-service beneficiaries.

(2) The Federal per diem payment amount is based on the Federal per diem base rate plus applicable adjustments as specified in § 412.424.

(3) During the transition period, payment is based on a blend of the Federal per diem payment amount as specified in § 412.424, and the facility-specific payment rate as specified in § 412.426.

(b) *Payment in full.* (1) The payment made under this subpart represents payment in full (subject to applicable deductibles and coinsurance as specified in subpart G of part 409 of this chapter) for inpatient operating and capital-related costs associated with furnishing Medicare covered services in an inpatient psychiatric facility, but not the cost of an approved medical education program as specified in § 413.75 through § 413.85 of this chapter.

(2) In addition to the Federal per diem payment amounts, inpatient psychiatric facilities receive payment for bad debts of Medicare beneficiaries, as specified in § 413.80 of this chapter.

[69 FR 66977, Nov. 15, 2004; 70 FR 19728, Apr. 1, 2005]

§ 412.424 Methodology for calculating the Federal per diem payment amount.

(a) *Data sources.* (1) To calculate the Federal per diem base rate (as specified in paragraph (b) of this section for inpatient psychiatric facilities, as specified in paragraph (b) of this section, CMS uses the following data sources:

(2) The best Medicare data available to estimate the average inpatient operating and capital-related costs per day made as specified in part 413 of this chapter.

(i) Patient and facility cost report data capturing routine and ancillary costs.

(ii) An appropriate wage index to adjust for wage differences.

(iii) An increase factor to adjust for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by inpatient psychiatric facilities.

(b) *Determining the average per diem cost of inpatient psychiatric facilities for FY 2002.* CMS determines the average inpatient operating, ancillary, and capital-related per diem cost for which payment is made to each inpatient psychiatric facility, using the available data described in paragraph (a) of this section.

(c) *Determining the Federal per diem base rate for cost reporting periods beginning on or after January 1, 2005 through June 30, 2006.* (1) *General.* Payment

under the inpatient psychiatric facility prospective payment system is based on a standardized per diem payment referred to as the Federal per diem base rate. The Federal per diem base rate is the adjusted cost for 1 day of inpatient hospital services in an inpatient psychiatric facility in a base year as described in paragraph (b) of this section. The adjusted cost per day is adjusted in accordance with paragraphs (c)(2) through (c)(5) of this section.

(2) *Update of the average per diem cost.* CMS applies the increase factor described in paragraph (a)(2)(iii) of this section to the updated average per diem cost to the midpoint of the January 1, 2005 through June 30, 2006, under the update methodology described in section 1886(b)(3)(B)(ii) of the Act.

(3) *Budget neutrality.* (i) CMS adjusts the updated average per diem cost so that the aggregate payments in the first 18 months (for January 1, 2005 through June 30, 2006) under the inpatient psychiatric facility prospective payment system are estimated to equal the amount that would have been made to the inpatient psychiatric facilities under part 413 of this chapter if the inpatient psychiatric facility prospective payment system described in this subpart were not implemented.

(ii) CMS evaluates the accuracy of the budget-neutrality adjustment within the first 5 years after implementation of the inpatient psychiatric facility prospective payment system. CMS may make a one-time prospective adjustment to the Federal per diem base rate to account for significant differences between the historical data on cost-based TEFRA payments (the basis of the budget-neutrality adjustment at the time of implementation) and estimates of TEFRA payments based on actual data from the first year of the prospective payment system.

(4) *Outlier payments.* CMS determines a reduction factor equal to the estimated proportion of outlier payments described in paragraph (d)(3)(i) of this section.

(5) *Standardization.* CMS determines a reduction factor to reflect estimated increases in the Federal per diem base rate as defined in §412.402 resulting from the facility-level and patient-level adjustments described in paragraph (d) of this section.

(6) *Computation of the Federal per diem base rate.* The Federal per diem base rate is computed as follows:

(i) For cost reporting periods beginning on or after January 1, 2005 and on or before June 30, 2006, the Federal per diem base rate is computed in accordance with paragraph (c) of this section.

(ii) For inpatient psychiatric facilities beginning on or after July 1, 2006, the Federal per diem base rate will be the Federal per diem base rate for the previous year, updated by an increase factor described in paragraph (a)(2)(iii) of this section.

(d) Determining the Federal per diem payment amount. The Federal per diem payment amount is the product of the Federal per diem base rate established under paragraph (c) of this section, the facility-level adjustments applicable to the inpatient psychiatric facility, patient-level adjustments and other policy adjustments applicable to the case.

(1) *Facility-level adjustments.* (i) *Adjustment for wages.* CMS adjusts the labor portion of the Federal per diem base rate to account for geographic differences in the area wage levels using an appropriate wage index. The application of the wage index is made on the basis of the location of the inpatient psychiatric facility in an urban or rural area as defined in §412.402.

(ii) *Rural location.* CMS adjusts the Federal per diem base rate for inpatient psychiatric facilities located in a rural area as defined in §412.402.

(iii) *Teaching adjustment.* CMS adjusts the Federal per diem base rate by a factor to account for indirect medical education costs.

(A) An inpatient psychiatric facility's teaching adjustment is based on the ratio of the number of residents training in the inpatient psychiatric facility divided by the facility's average daily census.

(B) The number of full-time equivalent residents used in calculating the teaching adjustment cannot exceed the number of full-time equivalent residents in a base year.

(*1*) The base year is the inpatient psychiatric facility's most recently filed

cost report filed with its fiscal intermediary before November 15, 2004. Residents with less than full-time status and residents rotating through the inpatient psychiatric facility for less than a full year will be counted in proportion to the time they spend in the inpatient psychiatric facility.

(*2*) The teaching status adjustment for new inpatient psychiatric facilities as defined in § 412.426 is made in accordance with § 413.79(e)(1)(i) and (ii).

(C) If an inpatient psychiatric facility has fewer full-time equivalent residents than in its base year payment of the teaching adjustment will be based on the actual number of full-time equivalent residents. The inpatient psychiatric facility may add residents in subsequent years up to its resident cap established under section (1)(iii)(B) of this paragraph.

(iv) *Inpatient psychiatric facilities located in Alaska and Hawaii.* CMS adjusts the non-labor portion of the Federal per diem base rate to reflect the higher cost of living of inpatient psychiatric facilities located in Alaska and Hawaii.

(v) *Adjustment for IPF with qualifying emergency departments.* (A) CMS adjusts the Federal per diem base rate to account for the costs associated with maintaining a qualifying emergency department. A qualifying emergency department is staffed and equipped to furnish a comprehensive array of emergency services and meets the requirements of § 489.24(b) and § 413.65.

(B) Where the inpatient psychiatric facility is part of an acute care hospital that has a qualifying emergency department as described in paragraph (d)(1)(v)(A) of this section and an individual patient is discharged to the inpatient psychiatric facility from that acute care hospital, CMS would not apply the emergency adjustment.

(2) *Patient-level adjustments.* (i) *Age.* CMS adjusts the Federal per diem base rate to account for patient age based on age groupings specified by CMS.

(ii) *Diagnosis-related group assignment.* The inpatient psychiatric facility must identify a principal diagnosis as specified in § 412.27(a) for each patient. CMS adjusts the Federal per diem base rate by a factor to account for the CMS inpatient psychiatric facility prospective payment system recognized diagnosis-related group assignment associated with each patient's principal diagnosis.

(iii) *Principal diagnosis.* The inpatient psychiatric facility must identify a principal psychiatric diagnosis as specified in § 412.27(a) for each patient. CMS adjusts the Federal per diem base rate by a factor to account for the diagnosis-related group assignment associated with the principal diagnosis, as specified by CMS.

(iv) *Comorbidities.* CMS adjusts the Federal per diem base rate by a factor to account for certain comorbidities as specified by CMS.

(v) *Variable per diem adjustments.* CMS adjusts the Federal per diem base rate by factors as specified by CMS to account for the cost of each day of inpatient psychiatric care relative to the cost of the median length of stay.

(3) *Other adjustments.* (i) *Outlier payments.* CMS provides an additional payment if an inpatient psychiatric facility's estimated total cost for a case exceeds a fixed dollar loss threshold as defined in § 412.402 plus the Federal payment amount for the case.

(A) The fixed dollar loss threshold is adjusted for the inpatient psychiatric facility's adjustments for wage area, teaching, rural location, and cost of living adjustment for facilities located in Alaska and Hawaii.

(B) The outlier payment equals a percentage of the difference between the IPF's estimated cost for the case and the adjusted threshold amount specified by CMS for each day of the inpatient stay.

(C) For discharges occurring in cost reporting periods beginning on or after January 1, 2005, outlier payments are subject to the adjustments specified at § 412.84(i) and § 412.84(m) of this part, except that national urban and rural median cost-to-charge ratios would be used instead of statewide average cost-to-charge ratios.

(ii) *Stop-loss payments.* CMS will provide additional payments during the transition period, specified in § 412.426(a)(1) through (3), to an inpatient psychiatric facility to ensure that aggregate payments under the prospective payment system are at least 70 percent of the amount the inpatient psychiatric facility would have

received under reasonable cost reimbursement had the prospective payment system not been implemented.

(iii) *Special payment provision for interrupted stays.* If a patient is discharged from an inpatient psychiatric facility and is admitted to the same or another inpatient psychiatric facility within 3 consecutive calendar days following the discharge, the case is considered to be continuous for the purposes listed below. The 3 consecutive calendar days begins with the day of discharge from the inpatient psychiatric facility and ends on midnight of day 3.

(A) Determining the appropriate variable per diem adjustment, as specified in paragraph (d)(2)(v) of this section, applicable to the case.

(B) Determining whether the total cost for a case meets the criteria for outlier payments, as specified in paragraph (d)(3)(i)(C) of this section.

(iv) Payment for electroconvulsive therapy treatments. CMS provides an additional payment to reflect the cost of electroconvulsive therapy treatments received by a patient during an inpatient psychiatric facility stay in a manner specified by CMS.

[69 FR 66977, Nov. 15, 2004; 70 FR 16729, Apr. 1, 2005]

§412.426 Transition period.

(a) *Duration of transition period and composition of the blended transition payment.* Except as provided in paragraph (c) of this section, for cost reporting periods beginning on or after January 1, 2005 through January 1, 2008, an inpatient psychiatric facility receives a payment comprised of a blend of the estimated Federal per diem payment amount, as specified in §412.424(c) and a facility-specific payment as specified under paragraph (b).

(1) For cost reporting periods beginning on or after January 1, 2005 and on or before January 1, 2006, payment is based on 75 percent of the facility-specific payment and 25 percent is based on the Federal per diem payment amount.

(2) For cost reporting periods beginning on or after January 1, 2006 and on or before January 1, 2007, payment is based on 50 percent of the facility-specific payment and 50 percent is based on the Federal per diem payment amount.

(3) For cost reporting periods beginning on or after January 1, 2007 and on or before January 1, 2008, payment is based on 25 percent of the facility-specific payment and 75 percent is based on the Federal per diem payment amount.

(4) For cost reporting periods beginning on or after July 1, 2008, payment is based entirely on the Federal per diem payment amount.

(b) *Calculation of the facility-specific payment.* The facility-specific payment is equal to the estimated payment for each cost reporting period in the transition period that would have been made without regard to this subpart. The facility's Medicare fiscal intermediary calculates the facility-specific payment for inpatient operating costs and capital costs in accordance with part 413 of this chapter.

(c) *Treatment of new inpatient psychiatric facilities.* New inpatient psychiatric facilities, are facilities that under present or previous ownership or both have their first cost reporting period as an IPF beginning on or after January 1, 2005. New IPFs are paid based on 100 percent of the Federal per diem payment amount.

[69 FR 66977, Nov. 15, 2004; 70 FR 16729, Apr. 1, 2005]

§412.428 Publication of Updates to the inpatient psychiatric facility prospective payment system.

CMS will publish annually in the FEDERAL REGISTER information pertaining to updates to the inpatient psychiatric facility prospective payment system. This information includes:

(a) A description of the methodology and data used to calculate the updated Federal per diem base payment amount.

(b) The rate of increase factor as described in 412.424(a)(2)(iii), which is based on the excluded hospital with capital market basket under the update methodology of 1886(b)(3)(B)(ii) of the Act for each year.

(c) The best available hospital wage index and information regarding whether an adjustment to the Federal per diem base rate is needed to maintain budget neutrality.

(d) Updates to the fixed dollar loss threshold in order to maintain the appropriate outlier percentage.

(e) Describe the ICD–9–CM coding changes and DRG classification changes discussed in the annual update to the hospital inpatient prospective payment system regulations.

(f) Update the electroconvulsive therapy adjustment by a factor specified by CMS.

§ 412.432 Method of payment under the inpatient psychiatric facility prospective payment system.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, an inpatient psychiatric facility receives payment under this subpart for inpatient operating cost and capital-related costs for each inpatient stay following submission of a bill.

(b) *Periodic interim payments (PIP).* (1) Criteria for receiving PIP.

(i) An inpatient psychiatric facility receiving payment under this subpart may receive PIP for Part A services under the PIP method subject to the provisions of § 413.64(h) of this chapter.

(ii) To be approved for PIP, the inpatient psychiatric facility must meet the qualifying requirements in § 413.64(h)(3) of this chapter.

(iii) A hospital that is receiving periodic interim payments also receives payment under this subpart for applicable services furnished by its excluded psychiatric unit.

(iv) As provided in § 413.64(h)(5) of this chapter, intermediary approval is conditioned upon the intermediary's best judgment as to whether payment can be made under the PIP method without undue risk of resulting in an overpayment to the provider.

(2) *Frequency of payment.* For facilities approved for PIP, the intermediary estimates the annual inpatient psychiatric facility's Federal per diem prospective payments, net of estimated beneficiary deductibles and coinsurance, and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. If the inpatient psychiatric facility has payment experience under the prospective payment system, the intermediary estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year. Each payment is made 2 weeks after the end of a biweekly period of service as specified in § 413.64(h)(6) of this chapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient psychiatric facility receives interim payments for less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP.* (i) *Request by the inpatient psychiatric facility.* Subject to the provisions of paragraph (b)(1)(iii) of this section, an inpatient psychiatric facility receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates PIP if the inpatient psychiatric facility no longer meets the requirements of § 413.64(h) of this chapter.

(c) *Interim payments for Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system.* For Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system, the intermediary determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to 1/26 of the total estimated amount. Each payment is made 2 weeks after the end of the biweekly period of service as specified in § 413.64(h)(6) of this chapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient psychiatric facility receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Outlier payments.* Additional payments for outliers are not made on an interim basis. Outlier payments are

made based on the submission of a discharge bill and represents final payment subject to the cost report settlement specified in §412.84(i) and §412.84(m).

(e) *Accelerated payments.* (1) *General rule.* Upon request, an accelerated payment may be made to an inpatient psychiatric facility that is receiving payment under this subpart and is not receiving PIP under paragraph (b) of this section if the inpatient psychiatric facility is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the inpatient psychiatric facility.

(ii) Due to an exceptional situation, there is a temporary delay in the inpatient psychiatric facility's preparation and submittal of bills to the intermediary beyond the normal billing cycle.

(2) *Approval of accelerated payment.* An inpatient psychiatric facility's request for an accelerated payment must be approved by the intermediary and CMS.

(3) *Amount of accelerated payment.* The amount of the accelerated payment is computed as a percent of the net payment for unbilled or unpaid covered services.

(4) *Recovery of accelerated payment.* Recovery of the accelerated payment is made by recoupment as inpatient psychiatric facility bills are processed or by direct payment by the inpatient psychiatric facility.

Subpart O—Prospective Payment System for Long-Term Care Hospitals

SOURCE: 67 FR 56049, Aug. 30, 2002, unless otherwise noted.

§412.500 Basis and scope of subpart.

(a) *Basis.* This subpart implements section 123 of Public Law 106–113, which provides for the implementation of a prospective payment system for long-term care hospitals described in section 1886(d)(1)(B)(iv) of the Act. This subpart also reflects the provisions of section 307 of Public Law 106–554, which state that the Secretary shall examine and may provide for appropriate adjustments to that system, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and disproportionate share adjustments consistent with section 1886(d)(5)(F) of the Act.

(b) *Scope.* This subpart sets forth the framework for the prospective payment system for long-term care hospitals, including the methodology used for the development of payment rates and associated adjustments and related rules. Under this system, for cost reporting periods beginning on or after October 1, 2002, payment for the operating and capital-related costs of inpatient hospital services furnished by long-term care hospitals is made on the basis of prospectively determined rates and applied on a per discharge basis.

§412.503 Definitions.

As used in this subpart—

CMS stands for the Centers for Medicare & Medicaid Services.

Discharge. A Medicare patient in a long-term care hospital is considered discharged when—

(1) For purposes of the long-term care hospital qualification calculation, as described in §412.23(e)(3), the patient is formally released;

(2) For purposes of payment, as described in §412.521(b), the patient stops receiving Medicare-covered long-term care services; or

(3) The patient dies in the long-term care facility.

Long-term care hospital prospective payment system rate year means the 12-month period of July 1 through June 30.

LTC-DRG stands for the diagnosis-related group used to classify patient discharges from a long-term care hospital based on clinical characteristics and average resource use, for prospective payment purposes.

Outlier payment means an additional payment beyond the standard Federal prospective payment for cases with unusually high costs.

QIO (formerly PRO or Peer Review Organization) stands for the Quality Improvement Organization.

§ 412.505 Conditions for payment under the prospective payment system for long-term care hospitals.

(a) *Long-term care hospitals subject to the prospective payment system.* To be eligible to receive payment under the prospective payment system specified in this subpart, a long-term care hospital must meet the criteria to be classified as a long-term care hospital set forth in § 412.23(e) for exclusion from the acute care hospital inpatient prospective payment systems specified in § 412.1(a)(1). This condition is subject to the special payment provisions of § 412.22(c), the provisions on change in hospital status of § 412.22(d), the provisions related to hospitals-within-hospitals under § 412.22(e), and the provisions related to satellite facilities under § 412.22(h).

(b) *General requirements.* (1) Effective for cost reporting periods beginning on or after October 1, 2002, a long-term care hospital must meet the conditions for payment of this section, § 412.22(e)(6) and (h)(5), and §§ 412.507 through § 412.511 to receive payment under the prospective payment system described in this subpart for inpatient hospital services furnished to Medicare beneficiaries.

(2) If a long-term care hospital fails to comply fully with these conditions for payment with respect to inpatient hospital services furnished to one or more Medicare beneficiaries, CMS may withhold (in full or in part) or reduce Medicare payment to the hospital.

§ 412.507 Limitation on charges to beneficiaries.

(a) *Prohibited charges.* Except as provided in paragraph (b) of this section, a long-term care hospital may not charge a beneficiary for any covered services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment system. If Medicare has paid the full LTC-DRG payment, that payment applies to the hospital's costs for services furnished until the high-cost outlier threshold is met. If Medicare pays less than the full LTC-DRG payment, that payment only applies to the hospital's costs for those costs or days used to calculate the Medicare payment.

(b) *Permitted charges.* (1) A long-term care hospital that receives a full LTC-DRG payment under this subpart for covered days in a hospital stay may charge the Medicare beneficiary only for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this subchapter, and for items and services as specified under § 489.20(a) of this chapter.

(2) A long-term care hospital that receives less than the full LTC-DRG payment for a short-stay case, in accordance with § 412.529, may only charge the Medicare beneficiary for the applicable deductible and coinsurance under §§ 409.82, 409.83, and 409.87 of this subchapter, for items and services as specified under § 489.20(a) of this chapter, and for services provided during the stay that were not the basis for the short-stay payment.

§ 412.508 Medical review requirements.

(a) *Admission and quality review.* A long-term care hospital must have an agreement with a QIO to have the QIO review, on an ongoing basis, the following:

(1) The medical necessity, reasonableness, and appropriateness of hospital admissions and discharges.

(2) The medical necessity, reasonableness, and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.523(d)(1) and 412.525(a).

(3) The validity of the hospital's diagnostic and procedural information.

(4) The completeness, adequacy, and quality of the services furnished in the hospital.

(5) Other medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

(b) *Physician acknowledgement.* Payment under the long-term care hospital prospective payment system is based in part on each patient's principal and secondary diagnoses and major procedures performed, as evidenced by the physician's entries in the patient's

medical record. The hospital must assure that physicians complete an acknowledgement statement to this effect in accordance with paragraphs (b)(1) and (b)(2) of this section.

(1) *Content of physician acknowledgement statement.* When a claim is submitted, the hospital must have on file a signed and dated acknowledgement from the attending physician that the physician has received the following notice:

NOTICE TO PHYSICIANS: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

(2) *Completion of acknowledgement.* The acknowledgement must be completed by the physician at the time that the physician is granted admitting privileges at the hospital, or before or at the time the physician admits his or her first patient. Existing acknowledgements signed by physicians already on staff remain in effect as long as the physician has admitting privileges at the hospital.

(c) *Denial of payment as a result of admissions and quality review.*

(1) If CMS determines, on the basis of information supplied by a QIO, that a hospital has misrepresented admissions, discharges, or billing information, or has taken an action that results in the unnecessary admission or unnecessary multiple admissions of an individual entitled to benefits under Part A, or other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries, CMS may, as appropriate—

(i) Deny payment (in whole or in part) under Part A with respect to inpatient hospital services provided for an unnecessary admission or subsequent readmission of an individual; or

(ii) Require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(2) When payment with respect to admission of an individual patient is denied by a QIO under paragraph (c)(1) of this section, and liability is not waived in accordance with §§411.400 through 411.402 of this chapter, notice and appeals are provided under procedures established by CMS to implement the provisions of section 1155 of the Act, Right to Hearing and Judicial Review.

(3) A determination under paragraph (c)(1) of this section, if it is related to a pattern of inappropriate admissions and billing practices that has the effect of circumventing the prospective payment system, is referred to the Department's Office of Inspector General for handling in accordance with §1001.301 of this title.

§412.509 Furnishing of inpatient hospital services directly or under arrangement.

(a) Subject to the provisions of §412.521(b), the applicable payments made under this subpart are payment in full for all inpatient hospital services, as defined in §409.10 of this chapter. Inpatient hospital services do not include the following:

(1) Physicians' services that meet the requirements of §415.102(a) of this subchapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioners and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse midwife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in §410.69 of this subchapter.

(b) Medicare does not pay any provider or supplier other than the long-term care hospital for services furnished to a Medicare beneficiary who is an inpatient of the hospital except for services described in paragraphs (a)(1) through (a)(6) of this section.

(c) The long-term care hospital must furnish all necessary covered services to the Medicare beneficiary who is an inpatient of the hospital either directly

or under arrangements (as defined in § 409.3 of this subchapter).

§ 412.511 Reporting and recordkeeping requirements.

A long-term care hospital participating in the prospective payment system under this subpart must meet the recordkeeping and cost reporting requirements of §§ 412.22(e)(6), 412.22(h)(5), 413.20, and 413.24 of this subchapter.

§ 412.513 Patient classification system.

(a) *Classification methodology.* CMS classifies specific inpatient hospital discharges from long-term care hospitals by long-term care diagnosis-related groups (LTC-DRGs) to ensure that each hospital discharge is appropriately assigned based on essential data abstracted from the inpatient bill for that discharge.

(b) *Assignment of discharges to LTC-DRGs.* (1) The classification of a particular discharge is based, as appropriate, on the patient's age, sex, principal diagnosis (that is, the diagnosis established after study to be chiefly responsible for causing the patient's admission to the hospital), secondary diagnoses, procedures performed, and the patient's discharge status.

(2) Each discharge from a long-term care hospital is assigned to only one LTC-DRG (related, except as provided in paragraph (b)(3) of this section, to the patient's principal diagnosis), regardless of the number of conditions treated or services furnished during the patient's stay.

(3) When the discharge data submitted by a hospital show a surgical procedure unrelated to a patient's principal diagnosis, the bill is returned to the hospital for validation and reverification. The LTC-DRG classification system provides a LTC-DRG, and an appropriate weighting factor, for those cases for which none of the surgical procedures performed are related to the principal diagnosis.

(c) *Review of LTC-DRG assignment.* (1) A hospital has 60 days after the date of the notice of the initial assignment of a discharge to a LTC-DRG to request a review of that assignment. The hospital may submit additional information as a part of its request.

(2) The intermediary reviews that hospital's request and any additional information and decides whether a change in the LTC-DRG assignment is appropriate. If the intermediary decides that a different LTC-DRG should be assigned, the case will be reviewed by the appropriate QIO as specified in § 476.71(c)(2) of this chapter.

(3) Following the 60-day period described in paragraph (c)(1) of this section, the hospital may not submit additional information with respect to the DRG assignment or otherwise revise its claim.

§ 412.515 LTC-DRG weighting factors.

For each LTC-DRG, CMS assigns an appropriate weight that reflects the estimated relative cost of hospital resources used within that group compared to discharges classified within other groups.

§ 412.517 Revision of LTC-DRG group classifications and weighting factors.

CMS adjusts the classifications and weighting factors annually to reflect changes in—

(a) Treatment patterns;

(b) Technology;

(c) Number of discharges; and

(d) Other factors affecting the relative use of hospital resources.

§ 412.521 Basis of payment.

(a) *Method of payment.*

(1) Under the prospective payment system, long-term care hospitals receive a predetermined payment amount per discharge for inpatient services furnished to Medicare beneficiaries.

(2) The amount of payment under the prospective payment system is based on the Federal payment rate established in accordance with § 412.523, including adjustments described in § 412.525, and, if applicable during a transition period, on a blend of the Federal payment rate and the cost-based reimbursement rate described in § 412.533.

(b) *Payment in full.*

(1) The payment made under this subpart represents payment in full (subject to applicable deductibles and coinsurance described in subpart G of part

409 of this subchapter) for covered inpatient operating costs as described in §412.2(c) and capital-related costs described in subpart G of part 413 of this subchapter associated with furnishing Medicare covered services in long-term care hospitals.

(2) In addition to payment based on prospective payment rates, long-term care hospitals may receive payments separate from payments under the prospective payment system for the following:

(i) The costs of approved medical education programs described in §§413.75 through 413.83, 413.85, and 413.87 of this subchapter.

(ii) Bad debts of Medicare beneficiaries, as provided in §413.89 of this subchapter.

(iii) A payment amount per unit for blood clotting factor provided to Medicare inpatients who have hemophilia.

(iv) Anesthesia services furnished by hospital employed nonphysician anesthetists or obtained under arrangements, as specified in §412.113(c)(2).

(v) The costs of photocopying and mailing medical records requested by a QIO, in accordance with §476.78(c) of this chapter.

(c) *Payment by workers' compensation, automobile medical, no-fault or liability insurance or an employer group health plan primary to Medicare.* If workers' compensation, automobile medical, no-fault, or liability insurance or an employer group health plan that is primary to Medicare pays in full or in part, payment is determined in accordance with the guidelines specified in §412.120(b).

(d) *Effect of change of ownership on payments under the prospective payment system.* When a hospital's ownership changes, as described in §489.18 of this chapter, the following rules apply:

(1) Payment for the operating and capital-related costs of inpatient hospital services for each patient, including outlier payments as provided in §412.525 and payments for hemophilia clotting factor costs as provided in paragraph (b)(2)(iii) of this section, are made to the entity that is the legal owner on the date of discharge. Payments are not prorated between the buyer and seller.

(i) The owner on the date of discharge is entitled to submit a bill for all inpatient hospital services furnished to a beneficiary regardless of when the beneficiary's coverage began or ended during a stay, or of how long the stay lasted.

(ii) Each bill submitted must include all information necessary for the intermediary to compute the payment amount, whether or not some of that information is attributable to a period during which a different party legally owned the hospital.

(2) Other payments for the direct costs of approved medical education programs, bad debts, anesthesia services furnished by hospital employed nonphysician anesthetists, and costs of photocopying and mailing medical records to the QIO as provided for under paragraphs (b)(2)(i), (ii), (iv), and (v) of this section are made to each owner or operator of the hospital (buyer and seller) in accordance with the principles of reasonable cost reimbursement.

(e) *Special payment provisions for patients in acute care hospitals that change classification status to LTCH status during a patient stay.* (1) If a patient is admitted to an acute care hospital and then the acute care hospital meets the criteria at §412.23(e) to be paid as a LTCH during the course of the patient's hospitalization, Medicare considers all the days of the patient stay in the facility (days prior to and after the designation of LTCH status) to be a single episode of LTCH care. Payment for the entire patient stay (days prior to and after the designation of LTCH status) will include the day and cost data for that patient at both the acute care hospital and the LTCH in determining the payment to the LTCH under this subpart. The requirements of this paragraph (e)(1) apply only to a patient stay in which a patient is in an acute care hospital and that hospital is designated as a LTCH on or after October 1, 2004.

(2) The days of the patient's stay prior to and after the hospital's designation as a LTCH as specified in

paragraph (e)(1) of this section are included for purposes of determining the beneficiary's length of stay.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 34162, June 6, 2003; 69 FR 49250, Aug. 11, 2004; 70 FR 47487, Aug. 12, 2005]

§ 412.523 Methodology for calculating the Federal prospective payment rates.

(a) *Data used*. To calculate the initial prospective payment rates for inpatient hospital services furnished by long-term care hospitals, CMS uses—

(1) The best Medicare data available; and

(2) A rate of increase factor to adjust for the most recent estimate of increases in the prices of an appropriate market basket of goods and services included in covered inpatient long-term care hospital services.

(b) *Determining the average costs per discharge for FY 2003*. CMS determines the average inpatient operating and capital-related costs per discharge for which payment is made to each inpatient long-term care hospital using the available data under paragraph (a)(1) of this section. The cost per discharge is adjusted to FY 2003 by a rate of increase factor, described in paragraph (a)(2) of this section, under the update methodology described in section 1886(b)(3)(B)(ii) of the Act for each year.

(c) *Determining the Federal prospective payment rates*.

(1) *General*. The Federal prospective payment rates will be established using a standard payment amount referred to as the standard Federal rate. The standard Federal rate is a standardized payment amount based on average costs from a base year that reflects the combined aggregate effects of the weighting factors and other adjustments.

(2) *Update the cost per discharge*. CMS applies the increase factor described in paragraph (a)(2) of this section to each hospital's cost per discharge determined under paragraph (b) of this section to compute the cost per discharge for FY 2003. Based on the updated cost per discharge, CMS estimates the payments that would have been made to each hospital for FY 2003 under Part 413 of this chapter without regard to the prospective payment system implemented under this subpart.

(3) *Computation of the standard Federal rate*. The standard Federal rate is computed as follows:

(i) *For FY 2003*. Based on the updated costs per discharge and estimated payments for FY 2003 determined in paragraph (c)(2) of this section, CMS computes a standard Federal rate for FY 2003 that reflects, as appropriate, the adjustments described in paragraph (d) of this section. The FY 2003 standard Federal rate is effective for discharges occurring in cost reporting periods beginning on or after October 1, 2002 through June 30, 2003.

(ii) *For long-term care hospital prospective payment system rate years beginning July 1, 2003 and after*. The standard Federal rate for long-term care hospital prospective payment system rate years beginning July 1, 2003 and after will be the standard Federal rate for the previous long-term care hospital prospective payment system rate year, updated by the increase factor described in paragraph (a)(2) of this section, and adjusted, as appropriate, as described in paragraph (d) of this section. For the rate year from July 1, 2003 through June 30, 2004, the updated and adjusted standard Federal rate will be offset by a budget neutrality factor to account for updating the FY 2003 standard Federal rate on July 1 rather than October 1.

(4) *Determining the Federal prospective payment rate for each LTC-DRG*. The Federal prospective payment rate for each LTC-DRG is the product of the weighting factors described in § 412.515 and the standard Federal rate described in paragraph (c)(3) of this section.

(d) *Adjustments to the standard Federal rate*. The standard Federal rate described in paragraph (c)(3) of this section will be adjusted for—

(1) *Outlier payments*. CMS adjusts the standard Federal rate by a reduction factor of 8 percent, the estimated proportion of outlier payments under the long-term care hospital prospective payment system, as described in § 412.525(a).

(2) *Budget neutrality*. CMS adjusts the Federal prospective payment rates for FY 2003 so that aggregate payments

under the prospective payment system are estimated to equal the amount that would have been paid to long-term care hospitals under Part 413 of this subchapter without regard to the prospective payment system implemented under this subpart, excluding the effects of sections 1886(b)(2) and (b)(3) of the Act.

(3) *One-time prospective adjustment.* The Secretary will review payments under this prospective payment system and may make a one-time prospective adjustment to the long-term care hospital prospective payment system rates by October 1, 2006, so that the effect of any significant difference between actual payments and estimated payments for the first year of the long-term care hospital prospective payment system is not perpetuated in the prospective payment rates for future years.

(e) *Calculation of the adjusted Federal prospective payment.* For each discharge, a long-term care hospital's Federal prospective payment is computed on the basis of the Federal prospective payment rate multiplied by the relative weight of the LTC-DRG assigned for that discharge. A hospital's Federal prospective payment rate will be adjusted, as appropriate, to account for outliers and other factors as specified in §412.525.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 34162, June 6, 2003]

§412.525 Adjustments to the Federal prospective payment.

(a) *Adjustments for high-cost outliers.* (1) CMS provides for an additional payment to a long-term care hospital if its estimated costs for a patient exceed the adjusted LTC-DRG payment plus a fixed-loss amount. For each long-term care hospital rate year, CMS determines a fixed-loss amount that is the maximum loss that a hospital can incur under the prospective payment system for a case with unusually high costs.

(2) The fixed-loss amount is determined for the long-term care hospital rate year using the LTC-DRG relative weights that are in effect on July 1 of the rate year.

(3) The additional payment equals 80 percent of the difference between the estimated cost of the patient care (determined by multiplying the hospital-specific cost-to-charge ratios by the Medicare allowable covered charge) and the sum of the adjusted Federal prospective payment for the LTC-DRG prospective payment system payment and the fixed-loss amount.

(4)(i) For discharges occurring on or after October 1, 2002 and before August 8, 2003, no reconciliations will be made to outlier payments upon cost report settlement to account for differences between the estimated cost-to-charge ratio and the actual cost-to-charge ratio of the case.

(ii) For discharges occurring on or after August 8, 2003, high-cost outlier payments are subject to the provisions of §§412.84(i)(1), (i)(3), and (i)(4) and (m) for adjustments of cost-to-charge ratios.

(iii) For discharges occurring on or after October 1, 2003, high-cost outlier payments are subject to the provisions of §412.84(i)(2) for adjustments to cost-to-charge ratios.

(b) *Adjustments for Alaska and Hawaii.* CMS adjusts the Federal prospective payment for the effects of a higher cost of living for hospitals located in Alaska and Hawaii.

(c) *Adjustments for area levels.* The labor portion of a long-term care hospital's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index (established by CMS), which reflects the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined in accordance with paragraph (c)(1) or (c)(2) of this section) of the hospital compared to the national average level of hospital wages and wage-related costs. The appropriate wage index (established by CMS) is updated annually.

(1) For cost reporting periods beginning on or after October 1, 2002, with respect to discharges occurring during the period covered by such cost reports but before July 1, 2005, the application of the wage index under the long-term care hospital prospective payment system is made on the basis of the location of the facility in an urban or rural area as defined in §412.62(f)(1)(ii) and (f)(1)(iii), respectively.

(2) For discharges occurring on or after July 1, 2005, the application of the wage index under the long-term care hospital prospective payment system is made on the basis of the location of the facility in an urban or rural area as defined in § 412.64(b)(1)(ii)(A) through (C).

(d) *Special payment provisions.* CMS adjusts the Federal prospective payment to account for—

(1) Short-stay outliers, as provided for in § 412.529; and

(2) A 3-day or less interruption of a stay and a greater than 3-day interruption of a stay, as provided for in § 412.531.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 34163, June 6, 2003; 68 FR 34515, June 9, 2003; 69 FR 25721, May 7, 2004; 70 FR 24222, May 6, 2005]

§ 412.529 Special payment provision for short-stay outliers.

(a) *Short-stay outlier defined.* ''Short-stay outlier'' means a discharge with a length of stay in a long-term care hospital that is up to and including five-sixths of the geometric average length of stay for each LTC-DRG.

(b) *Adjustment to payment.* CMS adjusts the hospital's Federal prospective payment to account for any case that is determined to be a short-stay outlier, as defined in paragraph (a) of this section, under the methodology specified in paragraph (c) of this section.

(c) *Method for determining the payment amount.* (1) Subject to the provisions of paragraph (c)(4) of this section, the adjusted payment amount for a short-stay outlier is the least of the following amounts:

(i) 120 percent of the LTC-DRG specific per diem amount determined under paragraph (c)(2) of this section multiplied by the length of stay of the discharge;

(ii) 120 percent of the cost of the case determined under paragraph (c)(3) of this section; or

(iii) The Federal prospective payment for the LTC-DRG.

(2) CMS calculates a per diem amount for short-stay outliers for each LTC-DRG by dividing the product of the standard Federal payment rate and the LTC-DRG weight by the geometric mean length of stay of the specific LTC-DRG.

(3) To determine the cost of a case, CMS uses the hospital-specific cost-to-charge ratio and the Medicare allowable charges for the case.

(4) Effective for discharges occurring on or after July 1, 2003, for long-term care hospitals described under § 412.23(e)(2)(ii), the adjusted payment amount for a short-stay outlier is determined under the formula set forth in paragraph (c)(1) of this section with the following substitution of the percentages specified for the LTG-DRG specific per diem amount and the cost of the case under paragraphs (c)(1)(i) and (c)(1)(ii) of this section:

(i) For the 1st year of the transition period, as specified at § 412.533(a)(1), the percentage is 195 percent.

(ii) For the 2nd year of the transition period, as specified at § 412.533(a)(2), the percentage is 193 percent;

(iii) For the 3rd year of the transition period, as specified at § 412.533(a)(3), the percentage is 165 percent;

(iv) For the 4th year of the transition period, as specified at § 412.533(a)(4), the percentage is 136 percent;

(v) For the 5th year of the transition period and after, as specified at § 412.533(a)(5), the percentage is 120 percent.

(5)(i) For discharges occurring on or after October 1, 2002 and before August 8, 2003, no reconciliations will be made to short-stay outlier payments upon cost report settlement to account for differences between cost-to-charge ratio and the actual cost-to-charge ratio of the case.

(ii) For discharges occurring on or after August 8, 2003, short-stay outlier payments are subject to the provisions of §§ 412.84(i)(1), (i)(3), and (i)(4) and (m) for adjustments of cost-to-charge ratios.

(iii) For discharges occurring on or after October 1, 2003, short-stay outlier payments are subject to the provisions of § 412.84(i)(2) for adjustments to cost-to-charge ratios.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 34163, June 6, 2003; 68 FR 34515, June 9, 2003]

§412.531 Special payment provisions when an interruption of a stay occurs in a long-term care hospital.

(a) *Definitions*—(1) *A 3-day or less interruption of stay defined.* ''A 3-day or less interruption of stay'' means a stay at a long-term care hospital during which a Medicare inpatient is discharged from the long-term care hospital to an acute care hospital, IRF, SNF, or the patient's home and readmitted to the same long-term care hospital within 3 days of the discharge from the long-term care hospital. The 3-day or less period begins with the date of discharge from the long-term care hospital and ends not later than midnight of the third day.

(2) *A greater than 3-day interruption of stay defined.* ''A greater than 3-day or less interruption of stay'' means A stay in a long-term care hospital during which a Medicare inpatient is discharged from the long-term care hospital to an acute care hospital, an IRF, or a SNF for a period of greater than 3 days but within the applicable fixed-day period specified in paragraphs (a)(2)(i) through (a)(2)(iii) of this section before being readmitted to the same long-term care hospital.

(i) For a discharge to an acute care hospital, the applicable fixed day period is between 4 and 9 consecutive days. The counting of the days begins on the date of discharge from the long-term care hospital and ends on the 9th date after the discharge.

(ii) For a discharge to an IRF, the applicable fixed day period is between 4 and 27 consecutive days. The counting of the days begins on the day of discharge from the long-term care hospital and ends on the 27th day after discharge.

(iii) For a discharge to a SNF, the applicable fixed day period is between 4 and 45 consecutive days. The counting of the days begins on the day of discharge from the long-term care hospital and ends on the 45th day after the discharge.

(b) *Methods of determining payments.* (1) For purposes of determining a Federal prospective payment—

(i) *Determining the length of stay.* In determining the length of stay of a patient at a long-term care hospital for payment purposes under this paragraph (b)—

(A) Except as specified in paragraphs (b)(1)(i)(B) and (b)(1)(i)(C) of this section, the number of days that a beneficiary spends away from the long-term care hospital during a 3-day or less interruption of stay under paragraph (a)(1) of this section is not included in determining the length of stay of the patient at the long-term care hospital when there is no outpatient or inpatient medical treatment or care provided at an acute care hospital or an IRF, or SNF services during the interruption that is considered a covered service delivered to the beneficiary.

(B) The number of days that a beneficiary spends away from a long-term care hospital during a 3-day or less interruption of stay under paragraph (a)(1) of this section are counted in determining the length of stay of the patient at the long-term care hospital if the beneficiary receives inpatient or outpatient medical care or treatment provided by an acute care hospital or IRF, or SNF services during the interruption. In the case where these services are provided during some, but not all days of a 3-day or less interruption, Medicare will include all days of the interruption in the long-term care hospitals day-count.

(C) The number of days that a beneficiary spends away from a long-term care hospital during a 3-day or less interruption of stay under paragraph (a)(1) of this section during which the beneficiary receives a procedure that is grouped to a surgical DRG under the inpatient prospective payment system in an acute care hospital during the 2005 and 2006 long-term care hospital prospective payment system rate year is not included in determining the length of stay of the patient at the long-term care hospital.

(D) The number of days that a beneficiary spends away from a LTCH during a greater than 3-day interruption of stay, as defined in paragraph (a)(2) of this section, is not included in determining the length of stay at the LTCH.

(ii) *Determining how payment is made.* (A) Subject to the provisions of paragraphs (b)(1)(ii)(A)(*1*) and (b)(1)(ii)(A)(*2*) of this section, for a 3-day or less interruption of stay under paragraph (a)(1)

of this section, the entire stay is paid as a single discharge from the long-term care hospital. CMS makes only one LTC-DRG payment for all portions of a long-term care stay.

(*1*) For a 3-day or less interruption of stay under paragraph (a)(1) of this section in which a long-term care hospital discharges a patient to an acute care hospital and the patient's treatment during the interruption is grouped into a surgical DRG under the acute care inpatient hospital prospective payment system, for the LTCH 2005 and 2006 rate years, CMS also makes a separate payment to the acute care hospital for the surgical DRG discharge in accordance with paragraph (b)(1)(i)(C) of this section.

(*2*) For a 3-day or less interruption of stay under paragraph (a)(1) of this section during which the patient receives inpatient or outpatient treatment or services at an acute care hospital or IRF, or SNF services, that are not otherwise excluded under § 412.509(a), the services must be provided under arrangements in accordance with § 412.509(c). CMS does not make a separate payment to the acute care hospital, IRF, or SNF for these services. The LTC-DRG payment made to the long-term care hospital is considered payment in full as specified in § 412.521(b).

(B) For a greater than 3-day interruption of stay under paragraph (a)(2) of this section, CMS will make only one LTC-DRG payment for all portions of a long-term care stay. CMS also separately pays the acute care hospital, the IRF, or the SNF in accordance with their respective payment systems, as specified in paragraph (c) of this section.

(iii) *Basis for the prospective payment.* Payment to the long-term care hospital is based on the patient's LTC-DRG that is determined in accordance with § 412.513(b).

(2) If the total number of days of a patient's length of stay in a long-term care hospital prior to and following a 3-day or less interruption of stay under paragraphs (b)(1)(i)(A), (B), or (C) of this section or a greater than 3-day interruption of stay under paragraph (b)(1)(i)(D) of this section is up to and including five-sixths of the geometric average length of stay of the LTC-DRG, CMS will make a Federal prospective payment for a short-stay outlier in accordance with § 412.529(c).

(3) If the total number of days of a patient's length of stay in a long-term care hospital prior to and following a 3-day or less interruption of stay under paragraphs (b)(1)(i)(A), (B), or (C) of this section or a greater than 3-day interruption of stay under paragraph (b)(1)(i)(D) of this section exceeds five-sixths of the geometric average length of stay for the LTC-DRG, CMS will make one full Federal LTC-DRG prospective payment for the case. An additional payment will be made if the patient's stay qualifies as a high-cost outlier, as set forth in § 412.525(a).

(4) Notwithstanding the provisions of paragraph (a) of this section, if a patient who has been discharged from a long-term care hospital to another facility and is readmitted to the long-term care hospital for additional treatment or services in the long-term care hospital following the stay at the other facility, the subsequent admission to the long-term care hospital is considered a new stay, even if the case is determined to fall into the same LTC-DRG, and the long-term care hospital will receive two separate Federal prospective payments if one of the following conditions are met:

(i) The patient has a length of stay in the acute care hospital that exceeds 9 days from the day of discharge from the long-term care hospital;

(ii) The patient has a length of stay in the IRF that exceeds 27 days from the day of discharge from the long-term care hospital; or

(iii) The patient has a length of stay in the SNF that exceeds 45 days from the day of discharge from the long-term care hospital.

(c) *Payments to an acute care hospital, an IRF, or a SNF during an interruption of a stay.*

(1) Payment to the acute care hospital for the acute care hospital stay following discharge from the long-term care hospital will be paid in accordance with the acute care hospital inpatient prospective payment systems specified in § 412.1(a)(1).

(2) Payment to an IRF for the IRF stay following a discharge from the

long-term care hospital will be paid in accordance with the IRF prospective payment system specified in § 412.624 of Subpart P of this part.

(3) Payment to a SNF for the SNF stay following a discharge from the long-term care hospital will be paid in accordance with the SNF prospective payment system specified in subpart J of Part 413 of this subchapter.

[67 FR 56049, Aug. 30, 2002, as amended at 69 FR 25721, May 7, 2004; 70 FR 24222, May 6, 2005]

§ 412.532 Special payment provisions for patients who are transferred to onsite providers and readmitted to a long-term care hospital.

(a) The policies set forth in this section apply in the following situations:

(1) A long-term care hospital (including a satellite facility) that is co-located within an onsite acute care hospital, an onsite IRF, or an onsite psychiatric facility or unit that meets the definition of a hospital-within-a-hospital under § 412.22(e).

(2) A satellite facility, as defined in § 412.22(f), that is co-located with the long-term care hospital.

(3) A SNF, as defined in section 1819(a) of the Act, that is co-located with the long-term care hospital.

(b) As used in this section, ''co-located'' or ''onsite'' facility means a hospital or unit that occupies space in a building also used by another hospital or unit or in one or more buildings on the same campus, as defined in § 413.65(a)(2) of this subchapter, as buildings used by another hospital or unit.

(c) If, during a cost reporting period, a long-term care hospital (including a satellite facility) discharges patients to an acute care hospital co-located with the long-term care hospital, as described in paragraph (a) of this section, and subsequently directly readmits more than 5 percent (that is, in excess of 5.0 percent) of the total number of its Medicare inpatients discharged from that acute care hospital, all such discharges to the co-located acute care hospital and the readmissions to the long-term care hospital will be treated as one discharge for that cost reporting period and one LTC-DRG payment will be made on the basis of each patient's initial principal diagnosis.

(d) If, during a cost reporting period, a long-term care hospital (including a satellite facility) discharges patients to an onsite IRF, an onsite psychiatric hospital or unit, or an onsite SNF, as described in paragraph (a) of this section, and subsequently directly readmits more than 5 percent (that is, in excess of 5.0 percent) of the total number of its Medicare inpatients discharged from the onsite IRF, the onsite psychiatric hospital or unit, or the onsite SNF, all such discharges to any of these providers and the readmissions to the LTCH will be treated as one discharge for that cost reporting period and one LTC-DRG payment will be made on the basis of the patient's initial principal diagnosis.

(e) For purposes of calculating the payment per discharge, payment for the entire stay at the long-term care hospital will be paid as a full LTC-DRG payment under § 412.523 or a short-stay outlier under § 412.529, depending on the duration of the entire stay.

(f) If the long-term care hospital does not meet the 5-percent thresholds specified under paragraph (c) or (d) of this section for discharges to the specified onsite providers and readmissions to the long-term care hospital during a cost reporting period, payment under the long-term care prospective payment system will be made, where applicable, under the policies on a 3-day or less interruption of a stay and a greater than 3-day interruption of a stay as specified in § 412.531.

(g) Payment to the onsite acute care hospital, the onsite IRF, the onsite psychiatric hospital or unit, and the onsite SNF for a beneficiary's stay in the specified onsite providers is subject to the applicable payment policies, including outliers and transfers, under the acute care hospital inpatient prospective payment system, the IRF prospective payment system, the SNF prospective payment system, or the excluded psychiatric hospital or unit cost-based reimbursement payment system, as appropriate.

(h) In determining whether a patient has previously been discharged and then admitted, all prior discharges are considered, even if the discharge occurs

late in one cost reporting period and the readmission occurs late in next cost reporting period.

(i)(1) A long-term care hospital or a satellite of a long-term care hospital that meets the criteria of § 412.22(e)(1) or (e)(2) or § 412.22(h)(1) through (h)(4) that occupies space in a building used by another hospital or in one or more entire buildings located on the same campus as buildings used by another hospital and must notify its fiscal intermediary and CMS in writing of its co-location and identify by name(s), address(es), and Medicare provider number(s) the onsite acute care hospital, onsite IRF, or onsite psychiatric facility or unit with which it is co-located.

(2) A long term care hospital or satellite of a long term care hospital that occupies space in a building used by a SNF or in one or more entire buildings located on the same campus as buildings used by a SNF must notify its fiscal intermediary and CMS in writing of its co-located status and identify by name, address and Medicare provider number the SNF with which it is co-located.

[67 FR 56049, Aug. 30, 2002, as amended at 69 FR 25721, May 7, 2004; 70 FR 24222, May 6, 2005]

§ 412.533 Transition payments.

(a) *Duration of transition periods.* Except for a long-term care hospital that makes an election under paragraph (c) of this section or for a long-term care hospital that is defined as new under § 412.23(e)(4), for cost reporting periods beginning on or after October 1, 2002, and before October 1, 2006, a long-term care hospital receives a payment comprised of a blend of the adjusted Federal prospective payment as determined under § 412.523, and the payment determined under the cost-based reimbursement rules under Part 413 of this subchapter.

(1) For cost reporting periods beginning on or after October 1, 2002 and before October 1, 2003, payment is based on 20 percent of the Federal prospective payment rate and 80 percent of the cost-based reimbursement rate.

(2) For cost reporting periods beginning on or after October 1, 2003 and before October 1, 2004, payment is based on 40 percent of the Federal prospective payment rate and 60 percent of the cost-based reimbursement rate.

(3) For cost reporting periods beginning on or after October 1, 2004 and before October 1, 2005, payment is based on 60 percent of the Federal prospective payment rate and 40 percent of the cost-based reimbursement rate.

(4) For cost reporting periods beginning on or after October 1, 2005 and before October 1, 2006, payment is based on 80 percent of the Federal prospective payment rate and 20 percent of the cost-based reimbursement rate.

(5) For cost reporting periods beginning on or after October 1, 2006, payment is based entirely on the adjusted Federal prospective payment rate.

(b) *Adjustments based on reconciliation of cost reports.* The cost-based percentage of the provider's total Medicare payment under paragraphs (a)(1) through (a)(4) of this section are subject to adjustments based on reconciliation of cost reports.

(c) *Election not to be paid under the transition period methodology.* A long-term care hospital may elect to be paid based on 100 percent of the Federal prospective rate at the start of any of its cost reporting periods during the 5-year transition periods specified in paragraph (a) of this section. Once a long-term care hospital elects to be paid based on 100 percent of the Federal prospective payment rate, it may not revert to the transition blend.

(1) *General requirement.* A long-term care hospital must notify its fiscal intermediary of its intent to elect to be paid based on 100 percent of the Federal prospective rate at the start of any of its cost reporting periods during the 5-year transition period specified in paragraph (a) of this section.

(2) *Notification requirement to make election.*

(i) The request by the long-term care hospital to make the election under paragraph (c)(1) of this section must be made in writing to the Medicare fiscal intermediary.

(ii) For cost reporting periods that begin on or after October 1, 2002 through November 30, 2002, the fiscal intermediary must receive the notification of the election before November 1, 2002.

(iii) For cost reporting periods that begin on or after December 1, 2002 through September 30, 2006, the fiscal intermediary must receive the notification of the election on or before the 30th day before the applicable cost reporting period begins.

(iv) The fiscal intermediary must receive the notification by the dates specified in paragraphs (c)(2)(ii) and (c)(2)(iii) of this section, regardless of any postmarks or anticipated delivery dates. Requests received, postmarked, or delivered by other means after the dates specified in paragraphs (c)(2)(ii) and (c)(2)(iii) of this section will not be accepted. If the date specified in paragraphs (c)(2)(ii) and (c)(2)(iii) of this section falls on a day that the postal service or other delivery sources are not open for business, the long-term care hospital is responsible for allowing sufficient time for the delivery of the notification before the deadline.

(v) If a long-term care hospital's notification is not received by the dates specified in paragraphs (c)(2)(ii) and (c)(2)(iii) of this section, payment will be based on the transition period rates specified in paragraphs (a)(1) through (a)(5) of this section.

(d) *Payments to new long-term care hospitals.* A new long-term care hospital, as defined in §412.23(e)(4), will be paid based on 100 percent of the standard Federal rate, as described in §412.523, with no transition payments, as described in §412.533(a)(1) through (a)(5).

§412.534 Special payment provisions for long-term care hospitals within hospitals and satellites of long-term care hospitals.

(a) *Scope.* The policies set forth in this section apply to discharges occurring in cost reporting periods beginning on or after October 1, 2004 from long-term care hospitals as described in §412.23(e)(2)(i) meeting the criteria in §412.22(e)(2), or satellite facilities of long-term care hospitals that meet the criteria in §412.22(h).

(b) *Patients admitted from hospitals not located in the same building or on the same campus as the long-term care hospital.* Payments to the long-term care hospital for patients admitted to the long-term hospital or to a satellite of the long-term care hospital from another hospital that is not the co-located hospital are made under the rules in this subpart with no adjustment under this section.

(c) *Patients admitted from the hospital located in the same building or on the same campus as the long-term care hospital or satellite facility.* Payments to the long-term care hospital for patients admitted to it or to its satellite facility from the co-located hospital will be made under either paragraph (c)(1) or paragraph (c)(2) of this section.

(1) Except as provided in paragraph (f) of this section, for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or its satellite facility has a discharged Medicare inpatient population of whom no more than 25 percent were admitted to the hospital or its satellite facility from the co-located hospital, payments are made under the rules at §412.500 through §412.541 in this subpart with no adjustment under this section.

(2) Except as provided in paragraph (d), (e), or (f) of this section, for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or satellite facility has a discharged Medicare inpatient population of whom more than 25 percent were admitted to the hospital or satellite facility from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital or satellite facility to exceed the 25 percent threshold for discharged patients who have been admitted from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount payable under this subpart that is equivalent to the amount that would be determined under the rules at Subpart A, §412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart at §412.500 through §412.541 with no adjustment under this section.

(3) In determining the percentage of patients admitted to the long-term care or satellite facility from the co-located hospital under paragraphs (c)(1) and (c)(2) of this section, patients on whose behalf an outlier payment was

made to the co-located hospital are not counted towards the 25 percent threshold.

(d) *Special treatment of rural hospitals.* (1) (1) Subject to paragraph (f) of this section, in the case of a long-term care hospital or satellite facility that is located in a rural area as defined in § 412.62(f) and is co-located with another hospital for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or satellite facility has a discharged Medicare inpatient population of whom more than 50 percent were admitted to the long-term care hospital or satellite facility from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital or satellite facility to exceed the 50 percent threshold for discharged patients who have been admitted from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount payable under this subpart that is equivalent to the amount that would be otherwise payable under Subpart A, § 412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart at § 412.500 through § 412.541 with no adjustment under this section.

(2) In determining the percentage of patients admitted from the co-located hospital under paragraph (d)(1) of this section, patients on whose behalf outlier payment was made at the co-located hospital are not counted toward the 50 percent threshold.

(e) *Special treatment of urban single or MSA dominant hospitals.* (1) Subject to paragraph (f) of this section, In the case of a long-term care hospital or satellite facility that is co-located with the only other hospital in the MSA or with a MSA dominant hospital as defined in paragraph (e)(4) of this section, for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or satellite facility has a discharged Medicare inpatient population of whom more than the percentage calculated under paragraph (e)(2) of this section were admitted to the hospital from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital to exceed the applicable threshold for discharged patients who have been admitted from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount under this subpart that is equivalent to the amount that otherwise would be determined under Subpart A, § 412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart with no adjustment under this section.

(2) For purposes of paragraph (e)(1) of this section, the percentage used is the percentage of total Medicare discharges in the Metropolitan Statistical Area in which the hospital is located that are from the co-located hospital for the cost reporting period for which the adjustment was made, but in no case is less than 25 percent or more than 50 percent.

(3) In determining the percentage of patients admitted from the co-located hospital under paragraph (e)(1) of this section, patients on whose behalf outlier payment was made at the co-located hospital are not counted toward the applicable threshold.

(4) For purposes of this paragraph, an ''MSA-dominant hospital'' is a hospital that has discharged more than 25 percent of the total hospital Medicare discharges in the MSA in which the hospital is located.

(f) *Transition period for long-term care hospitals and satellite facilities paid under this subpart.* In the case of a long-term care hospital or a satellite facility that is paid under the provisions of this Subpart O of Part 412 on October 1, 2004 or of a hospital that is paid under the provisions of this Subpart O on October 1, 2005 and whose qualifying period under § 412.23(e) began on or before October 1, 2004, the amount paid is calculated as specified below:

(1) For each discharge during the first cost reporting period beginning on or after October 1, 2004, and before October 1, 2005, the amount paid is the amount payable under this subpart with no adjustment under this section but the hospital may not exceed the percentage of patients admitted from

the host during its FY 2004 cost reporting period.

(2) For each discharge during the cost reporting period beginning on or after October 1, 2005, and before October 1, 2006, the percentage that may be admitted from the host with no payment adjustment may not exceed the lesser of the percentage of patients admitted from the host during its FY 2004 cost reporting period or 75 percent.

(3) For each discharge during the cost reporting period beginning on or after October 1, 2006, and before October 1, 2007, the percentage that may be admitted from the host with no payment adjustment may not exceed the lesser of the percentage of patients admitted from the host during its FY 2004 cost reporting period or 50 percent.

(4) For each discharge during cost reporting periods beginning on or after October 1, 2007, the percentage that may be admitted from the host with no payment adjustment may not exceed 25 percent or the applicable percentage determined under paragraph (d) or (e) of this section.

[69 FR 49251, Aug. 11, 2004, as amended at 69 FR 78529, Dec. 30, 2004]

§ 412.535 Publication of the Federal prospective payment rates.

CMS publishes information pertaining to the long-term care hospital prospective payment system effective for each annual update in the FEDERAL REGISTER.

(a) Information on the unadjusted Federal payment rates and a description of the methodology and data used to calculate the payment rates are published on or before May 1 prior to the start of each long-term care hospital prospective payment system rate year which begins July 1, unless for good cause it is published after May 1, but before June 1.

(b) Information on the LTC-DRG classification and associated weighting factors is published on or before August 1 prior to the beginning of each Federal fiscal year.

[68 FR 34163, June 6, 2003]

§ 412.541 Method of payment under the long-term care hospital prospective payment system.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, long-term care hospitals receive payment under this subpart for inpatient operating costs and capital-related costs for each discharge only following submission of a discharge bill.

(b) *Periodic interim payments.*

(1) *Criteria for receiving periodic interim payments.*

(i) A long-term care hospital receiving payment under this subpart may receive periodic interim payments (PIP) for Part A services under the PIP method subject to the provisions of § 413.64(h) of this subchapter.

(ii) To be approved for PIP, the long-term care hospital must meet the qualifying requirements in § 413.64(h)(3) of this subchapter.

(iii) As provided in § 413.64(h)(5) of this subchapter, intermediary approval is conditioned upon the intermediary's best judgment as to whether payment can be made under the PIP method without undue risk of the PIP resulting in an overpayment to the provider.

(2) *Frequency of payment.*

(i) For long-term care hospitals approved for PIP and paid solely under Federal prospective payment system rates under § 412.533(b), the intermediary estimates the long-term care hospital's Federal prospective payments net after estimated beneficiary deductibles and coinsurance and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year.

(ii) For long-term care hospitals approved for PIP and paid using the blended payment schedule specified in § 412.533(a) for cost reporting periods beginning on or after October 1, 2002, and before October 1, 2006, the intermediary estimates the hospital's portion of the Federal prospective payments net and the hospital's portion of the reasonable cost-based reimbursement payments net, after beneficiary deductibles and coinsurance, in accordance with the blended transition percentages specified in § 412.533(a), and makes biweekly payments equal to 1/26

of the total estimated amount of both portions of payments for the year.

(iii) If the long-term care hospital has payment experience under the long-term care hospital prospective payment system, the intermediary estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year.

(iv) Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6) of this subchapter.

(v) The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if a hospital receives interim payments for less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP.* (i) *Request by the hospital.* Subject to paragraph (b)(1)(iii) of this section, a long-term care hospital receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates PIP if the long-term care hospital no longer meets the requirements of § 413.64(h) of this subchapter.

(c) *Interim payments for Medicare bad debts and for Part A costs not paid under the prospective payment system.* For Medicare bad debts and for the costs of an approved education program, blood clotting factors, anesthesia services furnished by hospital-employed nonphysician anesthetists or obtained under arrangement, and photocopying and mailing medical records to a QIO, which are costs paid outside the prospective payment system, the intermediary determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to 1/26 of the total estimated amount. Each payment is made 2 weeks after the end of the biweekly period of service as described in § 413.64(h)(6) of this subchapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if a long-term care hospital receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Special interim payment for unusually long lengths of stay*—(1) *First interim payment.* A hospital that is not receiving periodic interim payments under paragraph (b) of this section may request an interim payment 60 days after a Medicare beneficiary has been admitted to the hospital. Payment for the interim bill is determined as if the bill were a final discharge bill and includes any outlier payment determined as of the last day for which services have been billed.

(2) *Additional interim payments.* A hospital may request additional interim payments at intervals of at least 60 days after the date of the first interim bill submitted under paragraph (d)(1) of this section. Payment for these additional interim bills, as well as the final bill, is determined as if the bill were the final bill with appropriate adjustments made to the payment amount to reflect any previous interim payment made under the provisions of this paragraph.

(e) *Outlier payments.* Additional payments for outliers are not made on an interim basis. The outlier payments are made based on the submission of a discharge bill and represent final payment.

(f) *Accelerated payments.* (1) *General rule.* Upon request, an accelerated payment may be made to a long-term care hospital that is receiving payment under this subpart and is not receiving PIP under paragraph (b) of this section if the hospital is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the long-term care hospital.

(ii) Due to an exceptional situation, there is a temporary delay in the hospital's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* A request by a long-term care hospital for an accelerated payment must be approved by the intermediary and by CMS.

(3) *Amount of payment*. The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment*. Recovery of the accelerated payment is made by recoupment as long-term care hospital bills are processed or by direct payment by the long-term care hospital.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 10988, Mar. 7, 2003]

Subpart P—Prospective Payment for Inpatient Rehabilitation Hospitals and Rehabilitation Units

SOURCE: 66 FR 41388, Aug. 7, 2001, unless otherwise noted.

§412.600 Basis and scope of subpart.

(a) *Basis*. This subpart implements section 1886(j) of the Act, which provides for the implementation of a prospective payment system for inpatient rehabilitation hospitals and rehabilitation units (in this subpart referred to as ''inpatient rehabilitation facilities'').

(b) *Scope*. This subpart sets forth the framework for the prospective payment system for inpatient rehabilitation facilities, including the methodology used for the development of payment rates and associated adjustments, the application of a transition phase, and related rules. Under this system, for cost reporting periods beginning on or after January 1, 2002, payment for the operating and capital costs of inpatient hospital services furnished by inpatient rehabilitation facilities to Medicare Part A fee-for-service beneficiaries is made on the basis of prospectively determined rates and applied on a per discharge basis.

§412.602 Definitions.

As used in this subpart—

Assessment reference date means the specific calendar day in the patient assessment process that sets the designated endpoint of the common patient observation period, with most patient assessment items usually referring back in time from this endpoint.

CMS stands for the Centers for Medicare & Medicaid Services.

Comorbidity means a specific patient condition that is secondary to the patient's principal diagnosis that is the primary reason for the inpatient rehabilitation stay.

Discharge. A Medicare patient in an inpatient rehabilitation facility is considered discharged when—

(1) The patient is formally released from the inpatient rehabilitation facility; or

(2) The patient dies in the inpatient rehabilitation facility.

Encode means entering data items into the fields of the computerized patient assessment software program.

Functional-related groups refers to the distinct groups under which inpatients are classified using proxy measurements of inpatient rehabilitation relative resource usage.

Interrupted stay means a stay at an inpatient rehabilitation facility during which a Medicare inpatient is discharged from the inpatient rehabilitation facility and returns to the same inpatient rehabilitation facility within 3 consecutive calendar days. The duration of the interruption of the stay of 3 consecutive calendar days begins with the day of discharge from the inpatient rehabilitation facility and ends on midnight of the third day.

Outlier payment means an additional payment beyond the standard Federal prospective payment for cases with unusually high costs.

Patient assessment instrument refers to a document that contains clinical, demographic, and other information on a patient.

Rural area means: For cost-reporting periods beginning on or after January 1, 2002, with respect to discharges occurring during the period covered by such cost reports but before October 1, 2005, an area as defined in §412.62(f)(1)(iii). For discharges occurring on or after October 1, 2005, rural area means an area as defined in §412.64(b)(1)(ii)(C).

Transfer means the release of a Medicare inpatient from an inpatient rehabilitation facility to another inpatient rehabilitation facility, a short-term, acute-care prospective payment hospital, a long-term care hospital as described in §412.23(e), or a nursing home

that qualifies to receive Medicare or Medicaid payments.

Urban area means: For cost-reporting periods beginning on or after January 1, 2002, with respect to discharges occurring during the period covered by such cost reports but before October 1, 2005, an area as defined in § 412.62(f)(1)(ii). For discharges occurring on or after October 1, 2005, urban area means an area as defined in § 412.64(b)(1)(ii)(A) and § 412.64(b)(1)(ii)(B).

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003; 70 FR 47952, Aug. 15, 2005]

§ 412.604 Conditions for payment under the prospective payment system for inpatient rehabilitation facilities.

(a) *General requirements.* (1) Effective for cost reporting periods beginning on or after January 1, 2002, an inpatient rehabilitation facility must meet the conditions of this section to receive payment under the prospective payment system described in this subpart for inpatient hospital services furnished to Medicare Part A fee-for-service beneficiaries.

(2) If an inpatient rehabilitation facility fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare Part A fee-for-service beneficiaries, CMS or its Medicare fiscal intermediary may, as appropriate—

(i) Withhold (in full or in part) or reduce Medicare payment to the inpatient rehabilitation facility until the facility provides adequate assurances of compliance; or

(ii) Classify the inpatient rehabilitation facility as an inpatient hospital that is subject to the conditions of subpart C of this part and is paid under the prospective payment systems specified in § 412.1(a)(1).

(b) *Inpatient rehabilitation facilities subject to the prospective payment system.* Subject to the special payment provisions of § 412.22(c), an inpatient rehabilitation facility must meet the general criteria set forth in § 412.22 and the criteria to be classified as a rehabilitation hospital or rehabilitation unit set forth in §§ 412.23(b), 412.25, and 412.29 for exclusion from the inpatient hospital prospective payment systems specified in § 412.1(a)(1).

(c) *Completion of patient assessment instrument.* For each Medicare Part A fee-for-service patient admitted to or discharged from an IRF on or after January 1, 2002, the inpatient rehabilitation facility must complete a patient assessment instrument in accordance with § 412.606.

(d) *Limitation on charges to beneficiaries*—(1) *Prohibited charges.* Except as provided in paragraph (d)(2) of this section, an inpatient rehabilitation facility may not charge a beneficiary for any services for which payment is made by Medicare, even if the facility's costs of furnishing services to that beneficiary are greater than the amount the facility is paid under the prospective payment system.

(2) *Permitted charges.* An inpatient rehabilitation facility receiving payment under this subpart for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this subchapter and for items or services as specified under § 489.20(a) of this chapter.

(e) *Furnishing of inpatient hospital services directly or under arrangement.* (1) Subject to the provisions of § 412.622(b), the applicable payments made under this subpart are payment in full for all inpatient hospital services, as defined in § 409.10 of this subchapter. Inpatient hospital services do not include the following:

(i) Physicians' services that meet the requirements of § 415.102(a) of this subchapter for payment on a fee schedule basis.

(ii) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse midwife services, as defined in section 1861(gg) of the Act.

(v) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(vi) Services of an anesthetist, as defined in § 410.69 of this chapter.

(2) Medicare does not pay any provider or supplier other than the inpatient rehabilitation facility for services furnished to a Medicare beneficiary who is an inpatient of the inpatient rehabilitation facility, except for services described in paragraphs (e)(1)(i) through (e)(1)(vi) of this section.

(3) The inpatient rehabilitation facility must furnish all necessary covered services to the Medicare beneficiary either directly or under arrangements (as defined in §409.3 of this subchapter).

(f) *Reporting and recordkeeping requirements.* All inpatient rehabilitation facilities participating in the prospective payment system under this subpart must meet the recordkeeping and cost reporting requirements of §§413.20 and 413.24 of this subchapter.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003]

§412.606 Patient assessments.

(a) *Admission orders.* At the time that each Medicare Part A fee-for-service patient is admitted, the inpatient rehabilitation facility must have physician orders for the patient's care during the time the patient is hospitalized.

(b) *Patient assessment instrument.* An inpatient rehabilitation facility must use the CMS inpatient rehabilitation facility patient assessment instrument to assess Medicare Part A fee-for-service inpatients who—

(1) Are admitted on or after January 1, 2002; or

(2) Were admitted before January 1, 2002, and are still inpatients as of January 1, 2002.

(c) *Comprehensive assessments.* (1) A clinician of the inpatient rehabilitation facility must perform a comprehensive, accurate, standardized, and reproducible assessment of each Medicare Part A fee-for-service inpatient using the inpatient rehabilitation facility patient assessment instrument specified in paragraph (b) of this section as part of his or her patient assessment in accordance with the schedule described in §412.610.

(2) A clinician employed or contracted by an inpatient rehabilitation facility who is trained on how to perform a patient assessment using the inpatient rehabilitation facility patient assessment instrument specified in paragraph (b) of the section must record appropriate and applicable data accurately and completely for each item on the patient assessment instrument.

(3) The assessment process must include—

(i) Direct patient observation and communication with the patient; and

(ii) When appropriate and to the extent feasible, patient data from the patient's physician(s), family, someone personally knowledgeable about the patient's clinical condition or capabilities, the patient's clinical record, and other sources.

§412.608 Patients' rights regarding the collection of patient assessment data.

(a) Before performing an assessment using the inpatient rehabilitation facility patient assessment instrument, a clinician of the inpatient rehabilitation facility must give a Medicare inpatient—

(1) The form entitled ''Privacy Act Statement—Health Care Records''; and

(2) The simplified plain language description of the Privacy Act Statement—Health Care Records which is a form entitled ''Data Collection Information Summary for Patients in Inpatient Rehabilitation Facilities.''

(b) The inpatient rehabilitation facility must document in the Medicare inpatient's clinical record that the Medicare inpatient has been given the documents specified in paragraph (a) of this section.

(c) By giving the Medicare inpatient the forms specified in paragraph (a) of this section the inpatient rehabilitation facility will inform the Medicare patient of—

(1) Their privacy rights under the Privacy Act of 1974 and 45 CFR 5b.4(a)(3); and

(2) The following rights:

(i) The right to be informed of the purpose of the collection of the patient assessment data;

(ii) The right to have the patient assessment information collected be kept confidential and secure;

(iii) The right to be informed that the patient assessment information

will not be disclosed to others, except for legitimate purposes allowed by the Federal Privacy Act and Federal and State regulations;

(iv) The right to refuse to answer patient assessment questions; and

(v) The right to see, review, and request changes on his or her patient assessment.

(d) The patient rights specified in this section are in addition to the patient rights specified in § 82.13 of this chapter.

[68 FR 45699, Aug. 1, 2003]

§ 412.610 Assessment schedule.

(a) *General*. For each Medicare Part A fee-for-service inpatient, an inpatient rehabilitation facility must complete a patient assessment instrument as specified in § 412.606 that covers a time period that is in accordance with the assessment schedule specified in paragraph (c) of this section.

(b) *Starting the assessment schedule day count*. The first day that the Medicare Part A fee-for-service inpatient is furnished Medicare-covered services during his or her current inpatient rehabilitation facility hospital stay is counted as day one of the patient assessment schedule.

(c) *Assessment schedules and reference dates*. The inpatient rehabilitation facility must complete a patient assessment instrument upon the Medicare Part A fee-for-service patient's admission and discharge as specified in paragraphs (c)(1) and (c)(2) of this section.

(1) *Admission assessment*.

(i) *General rule*. The admission assessment—

(A) Time period is a span of time that covers calendar days 1 through 3 of the patient's current Medicare Part A fee-for-service hospitalization;

(B) Has an admission assessment reference date that is the third calendar day of the span of time specified in paragraph (c)(1)(i)(A) of this section; and

(C) Must be completed by the calendar day that follows the admission assessment reference day.

(ii) *Exception to the general rule*. We may specify in the patient assessment instrument item-by-item guide and in other issued instructions, items that have a different admission assessment time period to most appropriately capture patient information for payment and quality of care monitoring objectives.

(2) *Discharge assessment*.

(i) *General rule*. The discharge assessment—

(A) Time period is a span of time that covers 3 calendar days, and is the discharge assessment reference date itself specified in paragraph (c)(2)(ii) of this section and the 2 calendar days prior to the discharge assessment reference date; and

(B) Must be completed on the 5th calendar day that follows the discharge assessment reference date specified in paragraph (c)(2)(ii) of this section with the discharge assessment reference date itself being counted as the first day of the 5 calendar day time span.

(ii) *Discharge assessment reference date*. The discharge assessment reference date is the actual day that the first of either of the following two events occurs:

(A) The patient is discharged from the inpatient rehabilitation facility; or

(B) The patient stops being furnished Medicare Part A fee-for-service inpatient rehabilitation services.

(iii) *Exception to the general rule*. We may specify in the patient assessment instrument item-by-item guide and in other issued instructions, items that have a different discharge assessment time period to most appropriately capture patient information for payment and quality of care monitoring objectives.

(d) *Encoding dates*. The admission and discharge patient assessments must be encoded by the 7th calendar day from the completion dates specified in paragraph (c) of this section.

(e) *Accuracy of the patient assessment data*. The encoded patient assessment data must accurately reflect the patient's clinical status at the time of the patient assessment.

(f) *Patient assessment instrument record retention*. An inpatient rehabilitation facility must maintain all patient assessment data sets completed on Medicare Part A fee-for-service patients within the previous 5 years either in a paper format in the patient's clinical record or in an electronic computer file

format that the inpatient rehabilitation facility can easily obtain.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003]

§412.612 Coordination of the collection of patient assessment data.

(a) *Responsibilities of the clinician.* A clinician of an inpatient rehabilitation facility who has participated in performing the patient assessment must have responsibility for—

(1) The accuracy and thoroughness of the specific data recorded by that clinician on the patient's assessment instrument; and

(2) The accuracy of the assessment reference date inserted on the patient assessment instrument completed under §412.610(c).

(b) *Penalty for falsification.*

(1) Under Medicare, an individual who knowingly and willfully—

(i) Completes a material and false statement in a patient assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or

(ii) Causes another individual to complete a material and false statement in a patient assessment is subject to a civil money penalty of not more than $5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

§412.614 Transmission of patient assessment data.

(a) *Data format. General rule.* The inpatient rehabilitation facility must encode and transmit data for each Medicare Part A fee-for-service inpatient—

(1) Using the computerized version of the patient assessment instrument available from us; or

(2) Using a computer program(s) that conforms to our standard electronic record layout, data specifications, and data dictionary, includes the required patient assessment instrument data set, and meets our other specifications.

(3) *Exception to the general rule.* When the inpatient rehabilitation facility does not submit claim data to Medicare in order to be paid for any of the services it furnished to a Medicare Part A fee-for-service inpatient, the inpatient rehabilitation facility is not required to, but may, transmit to Medicare the inpatient rehabilitation facility patient assessment data associated with the services furnished to that same Medicare Part A fee-for-service inpatient.

(b) *How to transmit data.* The inpatient rehabilitation facility must—

(1) Electronically transmit complete, accurate, and encoded data from the patient assessment instrument for each Medicare Part A fee-for-service inpatient to our patient data system in accordance with the data format specified in paragraph (a) of this section; and

(2) Transmit data using electronic communications software that provides a direct telephone connection from the inpatient rehabilitation facility to the our patient data system.

(c) *Transmission dates.* The inpatient rehabilitation facility must transmit both the admission patient assessment and the discharge patient assessments at the same time to the our patient data system by the 7th calendar day in the period beginning with the applicable patient assessment instrument encoding date specified in §412.610(d).

(d) *Late transmission penalty.* (1) We assess a penalty when an inpatient rehabilitation facility does not transmit the required data from the patient assessment instrument to the our patient data system in accordance with the transmission timeframe in paragraph (c) of this section.

(2) If the actual patient assessment data transmission date is later than 10 calendar days from the transmission date specified in paragraph (c) of this section, the patient assessment data is considered late and the inpatient rehabilitation facility receives a payment rate that is 25 percent less than the payment rate associated with a case-mix group.

(e) *Exemption to being assessed a penalty for transmitting the IRF-PAI data late.* CMS may waive the penalty specified in paragraph (d) of this section when, due to an extraordinary situation that is beyond the control of an inpatient rehabilitation facility, the

inpatient rehabilitation facility is unable to transmit the patient assessment data in accordance with paragraph (c) of this section. Only CMS can determine if a situation encountered by an inpatient rehabilitation facility is extraordinary and qualifies as a situation for waiver of the penalty specified in paragraph (d)(2) of this section. An extraordinary situation may be due to, but is not limited to, fires, floods, earthquakes, or similar unusual events that inflict extensive damage to an inpatient rehabilitation facility. An extraordinary situation may be one that produces a data transmission problem that is beyond the control of the inpatient rehabilitation facility, as well as other situations determined by CMS to be beyond the control of the inpatient rehabilitation facility. An extraordinary situation must be fully documented by the inpatient rehabilitation facility.

[66 FR 41388, Aug. 7, 2001, as amended at 68 FR 45699, Aug. 1, 2003]

§ 412.616 Release of information collected using the patient assessment instrument.

(a) *General.* An inpatient rehabilitation facility may release information from the patient assessment instrument only as specified in § 482.24(b)(3) of this chapter.

(b) *Release to the inpatient rehabilitation facility's agent.* An inpatient rehabilitation facility may release information that is patient-identifiable to an agent only in accordance with a written contract under which the agent agrees not to use or disclose the information except for the purposes specified in the contract and only to the extent the facility itself is permitted to do so under paragraph (a) of this section.

§ 412.618 Assessment process for interrupted stays.

For purposes of the patient assessment process, if a Medicare Part A fee-for-service patient has an interrupted stay, as defined under § 412.602, the following applies:

(a) *Assessment requirements.* (1) The initial case-mix group classification from the admission assessment remains in effect (that is, no new admission assessment is performed).

(2) When the patient has completed his or her entire rehabilitation episode stay, a discharge assessment must be performed.

(b) *Recording and encoding of data.* The clinician must record the interruption of the stay on the patient assessment instrument.

(c) If the interruption in the stay occurs during the admission assessment time period, the assessment reference date, completion date, and encoding date for the admission assessment are advanced by the same number of calendar days as the length of the patient's interruption in the stay.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002]

§ 412.620 Patient classification system.

(a) *Classification methodology.*

(1) A patient classification system is used to classify patients in inpatient rehabilitation facilities into mutually exclusive case-mix groups.

(2) For purposes of this subpart, case-mix groups are classes of Medicare patient discharges by functional-related groups that are based on a patient's impairment, age, comorbidities, functional capabilities, and other factors that may improve the ability of the functional-related groups to estimate variations in resource use.

(3) Data from admission assessments under § 412.610(c)(1) are used to classify a Medicare patient into an appropriate case-mix group.

(4) Data from the discharge assessment under § 412.610(c)(2) are used to determine the weighting factors under paragraph (b)(4) of this section.

(b) *Weighting factors.*

(1) *General.* An appropriate weight is assigned to each case-mix group that measures the relative difference in facility resource intensity among the various case-mix groups.

(2) *Short-stay outliers.* We will determine a weighting factor or factors for patients that are discharged and not transferred (as defined in § 412.602) within a number of days from admission as specified by us.

(3) *Patients who expire.* We will determine a weighting factor or factors for

patients who expire within a number of days from admission as specified by us.

(4) *Comorbidities*. We will determine a weighting factor or factors to account for the presence of a comorbidity, as defined in § 412.602, that is relevant to resource use in the classification system.

(c) *Revision of case-mix group classifications and weighting factors*. We may periodically adjust the case-mix groups and weighting factors to reflect changes in—

(1) Treatment patterns;

(2) Technology;

(3) Number of discharges; and

(4) Other factors affecting the relative use of resources.

§ 412.622 Basis of payment.

(a) *Method of payment*. (1) Under the prospective payment system, inpatient rehabilitation facilities receive a predetermined amount per discharge for inpatient services furnished to Medicare Part A fee-for-service beneficiaries.

(2) The amount of payment under the prospective payment system is based on the Federal payment rate, including adjustments described in § 412.624 and, if applicable, during a transition period, on a blend of the Federal payment rate and the facility-specific payment rate described in § 412.626.

(b) *Payment in full*. (1) The payment made under this subpart represents payment in full (subject to applicable deductibles and coinsurance as described in subpart G of part 409 of this subchapter) for inpatient operating and capital-related costs associated with furnishing Medicare covered services in an inpatient rehabilitation facility, but not for the cost of an approved medical education program described in §§ 413.75 and 413.85 of this chapter.

(2) In addition to payments based on prospective payment rates, inpatient rehabilitation facilities receive payments for the following:

(i) Bad debts of Medicare beneficiaries, as provided in § 413.89 of this chapter; and

(ii) A payment amount per unit for blood clotting factor provided to Medicare inpatients who have hemophilia.

[66 FR 41388, Aug. 7, 2001, as amended at 70 FR 47952, Aug. 15, 2005]

§ 412.624 Methodology for calculating the Federal prospective payment rates.

(a) *Data used*. To calculate the prospective payment rates for inpatient hospital services furnished by inpatient rehabilitation facilities, we use—

(1) The most recent Medicare data available, as of the date of establishing the inpatient rehabilitation facility prospective payment system, to estimate payments for inpatient operating and capital-related costs made under part 413 of this subchapter;

(2) An appropriate wage index to adjust for area wage differences;

(3) An increase factor to adjust for the most recent estimate of increases in the prices of an appropriate market basket of goods and services included in covered inpatient rehabilitation services; and

(4) Patient assessment data described in § 412.606 and other data that account for the relative resource utilization of different patient types.

(b) *Determining the average costs per discharge for fiscal year 2001*. We determine the average inpatient operating and capital costs per discharge for which payment is made to each inpatient rehabilitation facility using the available data specified under paragraph (a)(1) of this section. The cost per discharge is adjusted to fiscal year 2001 by an increase factor, described in paragraph (a)(3) of this section, under the update methodology described in section 1886(b)(3)(B)(ii) of the Act for each year through the midpoint of fiscal year 2001.

(c) *Determining the Federal prospective payment rates*—(1) *General*. The Federal prospective payment rates will be established using a standard payment amount referred to as the standard payment conversion factor. The standard payment conversion factor is a standardized payment amount based on average costs from a base year that reflects the combined aggregate effects of the weighting factors, various facility and case level adjustments, and other adjustments.

(2) *Update the cost per discharge*. CMS applies the increase factor described in paragraph (a)(3) of this section to the facility's cost per discharge determined under paragraph (b) of this section to

compute the cost per discharge for fiscal year 2002. Based on the updated cost per discharge, CMS estimates the payments that would have been made to the facility for fiscal year 2002 under part 413 of this chapter without regard to the prospective payment system implemented under this subpart.

(3) *Computation of the standard payment conversion factor*. The standard payment conversion factor is computed as follows:

(i) *For fiscal year 2002*. Based on the updated costs per discharge and estimated payments for fiscal year 2002 determined in paragraph (c)(2) of this section, CMS computes a standard payment conversion factor for fiscal year 2002, as specified by CMS, that reflects, as appropriate, the adjustments described in paragraph (d) of this section.

(ii) *For fiscal years after 2002*. The standard payment conversion factor for fiscal years after 2002 will be the standardized payments for the previous fiscal year updated by the increase factor described in paragraph (a)(3) of this section, including adjustments described in paragraph (d) of this section as appropriate.

(4) *Determining the Federal prospective payment rate for each case-mix group*. The Federal prospective payment rates for each case-mix group is the product of the weighting factors described in § 412.620(b) and the standard payment conversion factor described in paragraph (c)(3) of this section.

(d) *Adjustments to the standard payment conversion factor*. The standard payment conversion factor described in paragraph (c)(3) of this section will be adjusted for the following:

(1) *Outlier payments*. CMS determines a reduction factor equal to the estimated proportion of additional outlier payments described in paragraph (e)(5) of this section.

(2) *Budget neutrality*. CMS adjusts the Federal prospective payment rates for fiscal year 2002 so that aggregate payments under the prospective payment system, excluding any additional payments associated with elections not to be paid under the transition period methodology under § 412.626(b), are estimated to equal the amount that would have been made to inpatient rehabilitation facilities under part 413 of this chapter without regard to the prospective payment system implemented under this subpart.

(3) *Coding and classification changes*. CMS adjusts the standard payment conversion factor for a given year if CMS determines that revisions in case-mix classifications or weighting factors for a previous fiscal year (or estimates that those revisions for a future fiscal year) did result in (or would otherwise result in) a change in aggregate payments that are a result of changes in the coding or classification of patients that do not reflect real changes in case-mix.

(4) *Payment adjustment for Federal fiscal year 2006 and applicable Federal fiscal years*. CMS adjusts the standard payment conversion factor based on any updates to the adjustments specified in paragraph (e)(2), (e)(3), (e)(4) and (e)(7), of this section, and to any revision specified in § 412.620(c) by a factor as specified by the Secretary.

(e) *Calculation of the adjusted Federal prospective payment*. For each discharge, an inpatient rehabilitation facility's Federal prospective payment is computed on the basis of the Federal prospective payment rate that is in effect for its cost reporting period that begins in a Federal fiscal year specified under paragraph (c) of this section. A facility's Federal prospective payment rate will be adjusted, as appropriate, to account for area wage levels, payments for outliers and transfers, and for other factors as follows:

(1) *Adjustment for area wage levels*. The labor portion of a facility's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index. The application of the wage index is made on the basis of the location of the facility in an urban or rural area as defined in § 412.602. Adjustments or updates to the wage data used to adjust a facility's Federal prospective payment rate under paragraph (e)(1) of this section will be made in a budget neutral manner. CMS determines a budget neutral wage adjustment factor, based on any adjustment or update to the wage data, to apply to the standard payment conversion factor.

(2) *Adjustments for low-income patients.* We adjust the Federal prospective payment, on a facility basis, for the proportion of low-income patients that receive inpatient rehabilitation services as determined by us.

(3) *Adjustments for rural areas.* We adjust the Federal prospective payment by a factor, as specified by us for facilities located in rural areas, as defined in §412.602.

(4) *Adjustments for teaching hospitals.* For discharges on or after October 1, 2005, CMS adjusts the Federal prospective payment on a facility basis by a factor as specified by CMS for facilities that are teaching institutions or units of teaching institutions. This adjustment is made on a claim basis as an interim payment and the final payment in full for the claim is made during the final settlement of the cost report.

(5) *Adjustment for high-cost outliers.* CMS provides for an additional payment to an inpatient rehabilitation facility if its estimated costs for a patient exceed a fixed dollar amount (adjusted for area wage levels and factors to account for treating low-income patients, for rural location, and for teaching programs) as specified by CMS. The additional payment equals 80 percent of the difference between the estimated cost of the patient and the sum of the adjusted Federal prospective payment computed under this section and the adjusted fixed dollar amount. Effective for discharges occurring on or after October 1, 2003, additional payments made under this section will be subject to the adjustments at §412.84(i), except that national averages will be used instead of statewide averages. Effective for discharges occurring on or after October 1, 2003, additional payments made under this section will also be subject to adjustments at §412.84(m).

(6) *Adjustments related to the patient assessment instrument.* An adjustment to a facility's Federal prospective payment amount for a given discharge will be made, as specified under §412.614(d), if the transmission of data from a patient assessment instrument is late.

(7) Adjustments for certain facilities geographically redesignated in FY 2006.

(i) *General.* For a facility defined as an urban facility under §412.602 in FY 2006 that was previously defined as a rural facility in FY 2005 as the term rural was defined in FY 2005 under §412.602 and whose payment, after applying the adjustment under this paragraph, will be lower only because of being defined as an urban facility in FY 2006 and it no longer qualified for the rural adjustment under §412.624(e)(3) in FY 2006, CMS will adjust the facility's payment using the following method:

(A) For discharges occurring on or after October 1, 2005, and on or before September 30, 2006, the facility's payment will be increased by an adjustment of two thirds of its prior FY 2005 19.14 percent rural adjustment.

(B) For discharges occurring on or after October 1, 2006, and on or before September 30, 2007, the facility's payment will be increased by an adjustment of one third of its FY 2005 19.14 percent rural adjustment.

(ii) *Exception.* For discharges occurring on or after October 1, 2005 and on or before September 30, 2007, facilities whose payments, after applying the adjustment under this paragraph (e)(7)(i) of this section, will be higher because of being defined as an urban facility in FY 2006 and no longer being qualified for the rural adjustment under §412.624(e)(3) in FY 2006, CMS will adjust the facility's payment by a portion of the applicable additional adjustment described in paragraph (e)(7)(i)(A) and (e)(7)(i)(B) of this section as determined by us.

(f) *Special payment provision for patients that are transferred.*

(1) A facility's Federal prospective payment will be adjusted to account for a discharge of a patient who—

(i) Is transferred from the inpatient rehabilitation facility to another site of care, as defined in §412.602; and

(ii) Stays in the facility for a number of days that is less than the average length of stay for nontransfer cases in the case-mix group to which the patient is classified.

(2) We calculate the adjusted Federal prospective payment for patients who are transferred in the following manner:

(i) By dividing the Federal prospective payment by the average length of stay for nontransfer cases in the case-

mix group to which the patient is classified to equal the payment per day.

(ii) By multiplying the payment per day under paragraph (f)(2)(i) of this section by the number of days the patient stayed in the facility prior to being discharged to equal the per day payment amount.

(iii) By multiplying the payment per day under paragraph (f)(2)(i) by 0.5 to equal an additional one half day payment for the first day of the stay before the discharge.

(iv) By adding the per day payment amount under paragraph (f)(2)(ii) and the additional one-half day payment under paragraph (f)(2)(iii) to equal the unadjusted payment amount.

(v) By applying the adjustments described in paragraphs (e)(2), (e)(3), (e)(4), and (e)(7) of this section to the unadjusted payment amount determined in paragraph (f)(2)(iv) of this section to equal the adjusted transfer payment amount.

(g) *Special payment provision for interrupted stays.* When a patient in an inpatient rehabilitation facility has one or more interruptions in the stay, as defined in § 412.602 and as indicated on the patient assessment instrument in accordance with § 412.618(b), we will make payments in the following manner:

(1) *Patient is discharged and returns on the same day.* Payment for a patient who is discharged and returns to the same inpatient rehabilitation facility on the same day will be the adjusted Federal prospective payment under paragraph (e) of this section that is based on the patient assessment data specified in § 412.618(a)(1). Payment for a patient who is discharged and returns to the same inpatient rehabilitation facility on the same day will only be made to the inpatient rehabilitation facility.

(2) *Patient is discharged and does not return by the end of the same day.* Payment for a patient who is discharged and does not return on the same day but does return to the same inpatient rehabilitation facility by or on midnight of the third day, defined as an interrupted stay under § 412.602, will be—

(i) The adjusted Federal prospective payment under paragraph (e) of this section that is based on the patient assessment data specified in § 412.618(a)(1) made to the inpatient rehabilitation facility; and

(ii) If the reason for the interrupted patient stay is to receive inpatient acute care hospital services, an amount based on the prospective payment systems described in § 412.1(a)(1) made to the acute care hospital.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 45700, Aug. 1, 2003; 70 FR 47952, Aug. 15, 2005]

§ 412.626 Transition period.

(a) *Duration of transition period and proportion of the blended transition rate.* (1) Except for a facility that makes an election under paragraph (b) of this section, for cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002, an inpatient rehabilitation facility receives a payment comprised of a blend of the adjusted Federal prospective payment, as determined under § 412.624(e) or § 412.624(f) and a facility-specific payment as determined under paragraph (a)(2) of this section.

(i) For cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002, payment is based on 33⅓ percent of the facility-specific payment and 66⅔ percent of the adjusted FY 2002 Federal prospective payment.

(ii) For cost reporting periods beginning on or after October 1, 2002, payment is based entirely on the adjusted Federal prospective payment.

(2) *Calculation of the facility-specific payment.* The facility-specific payment is equal to the payment for each cost reporting period in the transition period that would have been made without regard to this subpart. The facility's Medicare fiscal intermediary calculates the facility-specific payment for inpatient operating costs and capital-related costs in accordance with part 413 of this chapter.

(b) *Election not to be paid under the transition period methodology.* An inpatient rehabilitation facility may elect a payment that is based entirely on the adjusted Federal prospective payment for cost reporting periods beginning before fiscal year 2003 without regard to the transition period percentages specified in paragraph (a)(1)(i) of this section.

(1) *General requirement.* An inpatient rehabilitation facility will be required to request the election under this paragraph (b) within 30 days of its first cost reporting period for which payment is based on the inpatient rehabilitation facility prospective payment system for cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002.

(2) *Notification requirement to make election.* The request by the inpatient rehabilitation facility to make the election under this paragraph (b) must be made in writing to the Medicare fiscal intermediary. The intermediary must receive the request on or before the 30th day before the applicable cost reporting period begins, regardless of any postmarks or anticipated delivery dates. Requests received, postmarked, or delivered by other means after the 30th day before the cost reporting period begins will not be approved. If the 30th day before the cost reporting period begins falls on a day that the postal service or other delivery sources are not open for business, the inpatient rehabilitation facility is responsible for allowing sufficient time for the delivery of the request before the deadline. If an inpatient rehabilitation facility's request is not received timely or is otherwise not approved, payment will be based on the transition period rate specified in paragraph (a)(1)(i) of this section.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002]

§ 412.628 Publication of the Federal prospective payment rates.

We publish information pertaining to the inpatient rehabilitation facility prospective payment system effective for each fiscal year in the FEDERAL REGISTER. This information includes the unadjusted Federal payment rates, the patient classification system and associated weighting factors, and a description of the methodology and data used to calculate the payment rates. This information is published on or before August 1 prior to the beginning of each fiscal year.

§ 412.630 Limitation on review.

Administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, is prohibited with regard to the establishment of the methodology to classify a patient into the case-mix groups and the associated weighting factors, the unadjusted Federal per discharge payment rates, additional payments for outliers and special payments, and the area wage index.

§ 412.632 Method of payment under the inpatient rehabilitation facility prospective payment system.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, an inpatient rehabilitation facility receives payment under this subpart for inpatient operating costs and capital-related costs for each discharge only following submission of a discharge bill.

(b) *Periodic interim payments.*

(1) *Criteria for receiving periodic interim payments.*

(i) An inpatient rehabilitation facility receiving payment under this subpart may receive periodic interim payments (PIP) for Part A services under the PIP method subject to the provisions of § 413.64(h) of this subchapter.

(ii) To be approved for PIP, the inpatient rehabilitation facility must meet the qualifying requirements in § 413.64(h)(3) of this subchapter.

(iii) Payments to a rehabilitation unit are made under the same method of payment as the hospital of which it is a part as described in § 412.116.

(iv) As provided in § 413.64(h)(5) of this chapter, intermediary approval is conditioned upon the intermediary's best judgment as to whether payment can be made under the PIP method without undue risk of its resulting in an overpayment to the provider.

(2) *Frequency of payment.* For facilities approved for PIP, the intermediary estimates the inpatient rehabilitation facility's Federal prospective payments net of estimated beneficiary deductibles and coinsurance and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. If the inpatient rehabilitation facility has payment experience under the prospective payment system, the intermediary estimates PIP based on that payment experience, adjusted for

projected changes supported by substantiated information for the current year. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6) of this subchapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient rehabilitation facility receives interim payments for less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP.* (i) *Request by the inpatient rehabilitation facility.* Subject to the provisions of paragraph (b)(1)(iii) of this section, an inpatient rehabilitation facility receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates PIP if the inpatient rehabilitation facility no longer meets the requirements of § 413.64(h) of this chapter.

(c) *Interim payments for Medicare bad debts and for Part A costs not paid under the prospective payment system.* For Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system, the intermediary determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to 1/26 of the total estimated amount. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6) of this chapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient rehabilitation facility receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Outlier payments.* Additional payments for outliers are not made on an interim basis. The outlier payments are made based on the submission of a discharge bill and represent final payment.

(e) *Accelerated payments.* (1) *General rule.* Upon request, an accelerated payment may be made to an inpatient rehabilitation facility that is receiving payment under this subpart and is not receiving PIP under paragraph (b) of this section if the inpatient rehabilitation facility is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the inpatient rehabilitation facility.

(ii) Due to an exceptional situation, there is a temporary delay in the inpatient rehabilitation facility's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* An inpatient rehabilitation facility's request for an accelerated payment must be approved by the intermediary and us.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as inpatient rehabilitation facility bills are processed or by direct payment by the inpatient rehabilitation facility.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

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AUTHORITY: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861 (v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww) Sec 124 of Pub. L. 106–113, 113 Stat. 1515.

SOURCE: 51 FR 34793, Sept. 30, 1986, unless otherwise noted.

Subpart A—Introduction and General Rules

§ 413.1 Introduction.

(a) *Basis, scope, and applicability*—(1) *Statutory basis*—(i) *Basic provisions.* (A) Section 1815 of the Act requires that the Secretary make interim payments to providers and periodically determine the amount that should be paid under Part A of Medicare to each provider for the services it furnishes.

(B) Section 1814(b) of the Act (for Part A) and section 1833(a) (for Part B) provide for payment on the basis of the lesser of a provider's reasonable costs or customary charges.

(C) Section 1861(v) of the Act defines ''reasonable cost''.

(ii) *Additional provisions.* (A) Section 1138(b) of the Act specifies the conditions for Medicare payment for organ procurement costs.

(B) Section 1814(j) of the Act provides for exceptions to the ''lower of costs or charges'' provisions.

(C) Sections 1815(a) and 1833(e) of the Act provide the Secretary with authority to request information from providers to determine the amount of Medicare payment due providers.

(D) Section 1833(a)(4) and (i)(3) of the Act provide for payment of a blended amount for certain surgical services furnished in a hospital's outpatient department.

(E) Section 1833(n) of the Act provides for payment of a blended amount for outpatient hospital diagnostic procedures such as radiology.

(F) Section 1834(c)(1)(C) of the Act establishes the method for determining Medicare payment for screening mammograms performed by hospitals.

(G) Section 1834(g) of the Act provides that payment for critical access hospital (CAH) outpatient services is the reasonable costs of the CAH in providing these services, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in part 415 of this chapter.

(H) Section 1881 of the Act authorizes payment for services furnished to ESRD patients.

(I) Section 1883 of the Act provides for payment for post-hospital SNF care

furnished by a rural hospital that has swing-bed approval.

(J) Sections 1886(a) and (b) of the Act impose a ceiling on the rate of increase in hospital inpatient costs.

(K) Section 1886(h) of the Act provides for payment to a hospital for the services of interns and residents in approved teaching programs on the basis of a ''per resident'' amount.

(2) *Scope*. This part sets forth regulations governing Medicare payment for services furnished to beneficiaries by—

(i) Hospitals and critical access hospitals (CAHs);

(ii) Skilled nursing facilities (SNFs);

(iii) Home health agencies (HHAs);

(iv) Comprehensive outpatient rehabilitation facilities (CORFs);

(v) End-stage renal disease (ESRD) facilities;

(vi) Providers of outpatient physical therapy and speech pathology services (OPTs); and

(vii) Organ procurement agencies (OPAs) and histocompatibility laboratories.

(3) *Applicability*. The payment principles and related policies set forth in this part are binding on CMS and its fiscal intermediaries, on the Provider Reimbursement Review Board, and on the entities listed in paragraph (a)(2) of this section.

(b) *Reasonable cost reimbursement*. Except as provided under paragraphs (c) through (h) of this section, Medicare is generally required, under section 1814(b) of the Act (for services covered under Part A) and under section 1833(a)(2) of the Act (for services covered under Part B) to pay for services furnished by providers on the basis of reasonable costs as defined in section 1861(v) of the Act, or the provider's customary charges for those services, if lower. Regulations implementing section 1861(v) are found generally in this part beginning at §413.5.

(c) *Outpatient maintenance dialysis and related services*. Section 1881 of the Act authorizes special rules for the coverage of and payment for services furnished to ESRD patients. Sections 413.170 and 413.174 implement various provisions of section 1881. In particular, §413.170 establishes a prospective payment method for outpatient maintenance dialysis services that applies both to hospital-based and independent ESRD facilities, and under which Medicare pays for both home and infacility dialysis services furnished on or after August 1, 1983.

(d) *Payment for inpatient hospital services*. (1) For cost reporting periods beginning before October 1, 1983, the amount paid for inpatient hospital services is determined on a reasonable cost basis.

(2) Payment to short-term general hospitals located in the 50 States and the District of Columbia for the operating costs of hospital inpatient services for cost reporting periods beginning on or after October 1, 1983, and for the capital-related costs of inpatient services for cost reporting periods beginning on or after October 1, 1991, are determined prospectively on a per discharge basis under part 412 of this chapter except as follows:

(i) Payment for capital-related costs for cost reporting periods beginning before October 1, 1991, medical education costs, kidney acquisition costs, and the costs of certain anesthesia services, is described in §412.113 of this chapter.

(ii) Payment to children's hospitals that are excluded from the prospective payment systems under subpart B of part 412 of this chapter, and hospitals outside the 50 States and the District of Columbia is on a reasonable cost basis, subject to the provisions of §413.40.

(iii) Payment to hospitals subject to a State reimbursement control system is described in paragraph (e) of this section.

(iv) For cost reporting periods beginning before January 1, 2005, payment to psychiatric hospitals (as well as separate psychiatric units (distinct parts) of short-term general hospitals) that are excluded under subpart B of part 412 of this chapter from the prospective payment system is on a reasonable cost basis, subject to the provisions of §413.40.

(v) For cost reporting periods beginning on or after January 1, 2005, payment to inpatient psychiatric facilities that meet the conditions of §412.404 of this chapter, is made under the prospective payment system described in subpart N of part 412 of this chapter.

(vi) For cost reporting periods beginning before January 1, 2002, payment to rehabilitation hospitals (as well as separate rehabilitation units (distinct parts) of short-term general hospitals), that are excluded under subpart B of part 412 of this subchapter from the prospective payment systems is made on a reasonable cost basis, subject to the provisions of § 413.40.

(vii) For cost reporting periods beginning on or after January 1, 2002, payment to rehabilitation hospitals (as well as separate rehabilitation units (distinct parts) of short-term general hospitals) that meet the conditions of § 412.604 of this chapter is based on prospectively determined rates under subpart P of part 412 of this subchapter.

(viii) For cost reporting periods beginning before October 1, 2002, payment to long-term care hospitals that are excluded under subpart B of Part 412 of this subchapter from the prospective payment systems is on a reasonable cost basis, subject to the provisions of § 413.40.

(ix) For cost reporting periods beginning on or after October 1, 2002, payment to the long-term hospitals that meet the condition for payment of §§ 412.505 through 412.511 of this subchapter is based on prospectively determined rates under subpart O of Part 412 of this subchapter.

(e) *State reimbursement control systems.* Beginning October 1, 1983, Medicare reimbursement for inpatient hospital services may be made in accordance with a State reimbursement control system rather than under the Medicare reimbursement principles set forth in this part, if the State system is approved by CMS. Regulations implementing this alternative reimbursement authority are set forth in subpart C of part 403 of this chapter.

(f) *Services of qualified nonphysician anesthetists.* For cost reporting periods, or any part of a cost reporting period, beginning on or after January 1, 1989, costs incurred for the services of qualified nonphysician anesthetists are not paid on a reasonable cost basis unless the provisions of § 412.113(c)(2) of this chapter apply. These services are paid under the special rules set forth in § 405.553 of this chapter.

(g) *Payment for services furnished in SNFs.* (1) Except as specified in paragraph (g)(2)(ii) of this section, the amount paid for services furnished in cost reporting periods beginning before July 1, 1998, is determined on a reasonable cost basis or, where applicable, in accordance with the prospectively determined payment rates for low-volume SNFs established under section 1888(d) of the Act, as set forth in subpart I of this part.

(2) The amount paid for services (other than those described in § 411.15(p)(2) of this chapter)—

(i) That are furnished in cost reporting periods beginning on or after July 1, 1998, to a resident who is in a covered Part A stay, is determined in accordance with the prospectively determined payment rates for SNFs established under section 1888(e) of the Act, as set forth in subpart J of this part.

(ii) That are furnished on or after July 1, 1998, to a resident who is not in a covered Part A stay, is determined in accordance with any applicable Part B fee schedule or, for a particular item or service to which no fee schedule applies, by using the existing payment methodology utilized under Part B for such item or service.

(h) *Payment for services furnished by HHAs.* The amount paid for home health services as defined in section 1861(m) of the Act (except durable medical equipment and the covered osteoporosis drug as provided for in that section) that are furnished beginning on or after October 1, 2000 to an eligible beneficiary under a home health plan of care is determined according to the prospectively determined payment rates for HHAs set forth in part 484, subpart E of this chapter.

[51 FR 34793, Sept. 30, 1986, as amended at 57 FR 33898, July 31, 1992; 57 FR 39829, Sept. 1, 1992; 58 FR 30670, May 26, 1993; 59 FR 6578, Feb. 11, 1994; 60 FR 33136, June 27, 1995; 60 FR 37594, July 21, 1995; 60 FR 50441, Sept. 29, 1995; 62 FR 31, Jan. 2, 1997; 62 FR 46032, 46037, Aug. 29, 1997; 63 FR 26309, May 12, 1998; 65 FR 18537, Apr. 7, 2000; 65 FR 40535, June 30, 2000; 65 FR 41211, July 3, 2000; 65 FR 46796, July 31, 2000; 66 FR 41394, Aug. 7, 2001; 67 FR 44077, July 1, 2002; 67 FR 56055, Aug. 30, 2002; 69 FR 66981, Nov. 15, 2004]

§413.5 Cost reimbursement: General.

(a) In formulating methods for making fair and equitable reimbursement for services rendered beneficiaries of the program, payment is to be made on the basis of current costs of the individual provider, rather than costs of a past period or a fixed negotiated rate. All necessary and proper expenses of an institution in the production of services, including normal standby costs, are recognized. Furthermore, the share of the total institutional cost that is borne by the program is related to the care furnished beneficiaries so that no part of their cost would need to be borne by other patients. Conversely, costs attributable to other patients of the institution are not to be borne by the program. Thus, the application of this approach, with appropriate accounting support, will result in meeting actual costs of services to beneficiaries as such costs vary from institution to institution. However, payments to providers of services for services furnished Medicare beneficiaries are subject to the provisions of §§413.13 and 413.30.

(b) Putting these several points together, certain tests have been evolved for the principles of reimbursement and certain goals have been established that they should be designed to accomplish. In general terms, these are the tests or objectives:

(1) That the methods of reimbursement should result in current payment so that institutions will not be disadvantaged, as they sometimes are under other arrangements, by having to put up money for the purchase of goods and services well before they receive reimbursement.

(2) That, in addition to current payment, there should be retroactive adjustment so that increases in costs are taken fully into account as they actually occurred, not just prospectively.

(3) That there be a division of the allowable costs between the beneficiaries of this program and the other patients of the provider that takes account of the actual use of services by the beneficiaries of this program and that is fair to each provider individually.

(4) That there be sufficient flexibility in the methods of reimbursement to be used, particularly at the beginning of the program, to take account of the great differences in the present state of development of recordkeeping.

(5) That the principles should result in the equitable treatment of both nonprofit organizations and profit-making organizations.

(6) That there should be a recognition of the need of hospitals and other providers to keep pace with growing needs and to make improvements.

(c) As formulated herein, the principles given recognition to such factors as depreciation, interest, bad debts, educational costs, compensation of owners, and an allowance for a reasonable return on equity capital (in the case of certain proprietary providers). With respect to allowable costs some items of inclusion and exclusion are:

(1) An appropriate part of the net cost of approved educational activities will be included.

(2) Costs incurred for research purposes, over and above usual patient care, will not be included.

(3) [Reserved]

(4) The value of services provided by nonpaid workers, as members of an organization (including services of members of religious orders) having an agreement with the provider to furnish such services, is includable in the amount that would be paid others for similar work.

(5) Discounts and allowances received on the purchase of goods or services are reductions of the cost to which they relate.

(6) Bad debts growing out of the failure of a beneficiary to pay the deductible, or the coinsurance, will be reimbursed (after bona fide efforts at collection).

(7) Charity and courtesy allowances are not includable, although ''fringe benefit'' allowances for employees under a formal plan will be includable as part of their compensation.

(8) A reasonable allowance of compensation for the services of owners in profitmaking organizations will be allowed providing their services are actually performed in a necessary function.

(9) Reasonable cost of physicians' direct medical and surgical services (including supervision of interns and residents in the care of individual patients) furnished in a teaching hospital may be

reimbursed as a provider cost (as described in § 415.162 of this chapter) if elected as provided for in § 415.160 of this chapter.

(d) In developing these principles of reimbursement for the Medicare program, all of the considerations inherent in allowances for depreciation were studied. The principles, as presented, provide options to meet varied situations. Depreciation will essentially be on an historical cost basis but since many institutions do not have adequate records of old assets, the principles provide an optional allowance in lieu of such depreciation for assets acquired before 1966. For assets acquired after 1965, the historical cost basis must be used. All assets actually in use for production of services for Medicare beneficiaries will be recognized even though they may have been fully or partially depreciated for other purposes. Assets financed with public funds may be depreciated. Although funding of depreciation is not required, there is an incentive for it since income from funded depreciation is not considered as an offset which must be taken to reduce the interest expense that is allowable as a program cost.

(e) A return on the equity capital of proprietary facilities, as described in § 413.157, is an allowance in addition to the reasonable cost of covered services furnished to beneficiaries.

(f) Renal dialysis items and services furnished under the ESRD provision are reimbursed and reported under §§ 413.170 and 413.174 respectively. For special rules concerning health maintenance organizations (HMOs), and providers of services and other health care facilities that are owned or operated by an HMO, or related to an HMO by common ownership or control, see §§ 417.242(b)(14) and 417.250(c) of this chapter.

[51 FR 34793, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987; 57 FR 39829, Sept. 1, 1992; 60 FR 63189, Dec. 8, 1995; 61 FR 63748, Dec. 2, 1996]

§ 413.9 Cost related to patient care.

(a) *Principle.* All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries. Reasonable cost includes all necessary and proper costs incurred in furnishing the services, subject to principles relating to specific items of revenue and cost. However, for cost reporting periods beginning after December 31, 1973, payments to providers of services are based on the lesser of the reasonable cost of services covered under Medicare and furnished to program beneficiaries or the customary charges to the general public for such services, as provided for in § 413.13.

(b) *Definitions*—(1) *Reasonable cost.* Reasonable cost of any services must be determined in accordance with regulations establishing the method or methods to be used, and the items to be included. The regulations in this part take into account both direct and indirect costs of providers of services. The objective is that under the methods of determining costs, the costs with respect to individuals covered by the program will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by the program. These regulations also provide for the making of suitable retroactive adjustments after the provider has submitted fiscal and statistical reports. The retroactive adjustment will represent the difference between the amount received by the provider during the year for covered services from both Medicare and the beneficiaries and the amount determined in accordance with an accepted method of cost apportionment to be the actual cost of services furnished to beneficiaries during the year.

(2) *Necessary and proper costs.* Necessary and proper costs are costs that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. They are usually costs that are common and accepted occurrences in the field of the provider's activity.

(c) *Application.* (1) It is the intent of Medicare that payments to providers of services should be fair to the providers, to the contributors to the Medicare trust funds, and to other patients.

(2) The costs of providers' services vary from one provider to another and

the variations generally reflect differences in scope of services and intensity of care. The provision in Medicare for payment of reasonable cost of services is intended to meet the actual costs, however widely they may vary from one institution to another. This is subject to a limitation if a particular institution's costs are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(3) The determination of reasonable cost of services must be based on cost related to the care of Medicare beneficiaries. Reasonable cost includes all necessary and proper expenses incurred in furnishing services, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. However, if the provider's operating costs include amounts not related to patient care, specifically not reimbursable under the program, or flowing from the provision of luxury items or services (that is, those items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services), such amounts will not be allowable. The reasonable cost basis of reimbursement contemplates that the providers of services would be reimbursed the actual costs of providing quality care however widely the actual costs may vary from provider to provider and from time to time for the same provider.

[51 FR 34795, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986]

§ 413.13 Amount of payment if customary charges for services furnished are less than reasonable costs.

(a) *Definitions.* As used in this section—

Customary charges means the regular rates that providers charge both beneficiaries and other paying patients for the services furnished to them.

Fair compensation means the reasonable cost of covered services.

Nominal charge means a charge equal to 60 percent or less of the reasonable cost of a service.

Public provider means a provider operated by a Federal, State, county, city, or other local government agency or instrumentality.

Reasonable cost means cost actually incurred, to the extent that cost is necessary for the efficient delivery of the service, and subject to the exclusions specified in paragraph (d) of this section.

(b) *Application of the lesser of costs or charges (LCC) principle.*—(1) *General rule.* Except as provided in paragraph (c) of this section, CMS pays providers the lesser of the reasonable cost or the customary charges for services furnished to Medicare beneficiaries. Reasonable cost and customary charges are compared separately for Part A services and Part B services.

(2) *Example.* (i) A provider's reasonable cost for covered services furnished to Medicare beneficiaries during a cost reporting period is $125,000.

(ii) The provider's customary charges for those services is $110,000.

(iii) CMS pays the provider $110,000 less the deductible and coinsurance amounts for which the beneficiaries are responsible.

(c) *Exceptions to the LCC principle.* (1) *Providers not subject to the LCC principle.*

CMS pays the following providers the fair compensation for the services they furnish:

(i) CORFs.

(ii) Public providers that furnish services free of charge or at a nominal charge.

(iii) Any provider that requests payment of fair compensation and can demonstrate to its intermediary that a significant portion of its patients are low income and that its charges are less than costs because its customary practice is to charge patients on the basis of their ability to pay.

(2) *Services not subject to the LCC principle.* The following services are not subject to the LCC principle:

(i) *Part A inpatient hospital services.* Inpatient hospital services are not subject to the LCC principle if they are subject to either of the following:

(A) The prospective payment system under part 412 of this chapter.

(B) The rate of increase limits set forth in § 413.40.

(ii) *Facility services related to ambulatory surgical procedures performed in outpatient hospital departments.* Facility services related to ambulatory surgical procedures performed in hospital outpatient departments are subject to the payment methodology set forth in § 413.118.

(iii) *Services furnished by a critical access hospital (CAH).* Inpatient and outpatient services furnished by a CAH are subject to the payment methodology set forth in § 413.70.

(iv) *Hospital outpatient radiology services.* Hospital outpatient radiology services are subject to the payment methodology set forth in § 413.122.

(v) *Other diagnostic procedures performed by a hospital on an outpatient basis.* Other outpatient diagnostic procedures are subject to the payment methodology set forth in § 413.122.

(vi) *Skilled nursing facility services.* Skilled nursing facility services subject to the payment methodology set forth in §§ 413.330 *et seq.*

(d) *Exclusions from reasonable cost.* For purposes of comparison with customary charges under this section, reasonable cost does not include the following:

(1) Payments made to a provider as reimbursement for bad debts arising from noncollection of Medicare deductible and coinsurance amounts, as provided in § 413.89.

(2) Amounts that represent the recovery of excess depreciation resulting from termination from the Medicare program or a decrease in Medicare utilization applicable to prior cost reporting periods, as provided in § 413.134.

(3) Amounts that result from disposition of depreciable assets, applicable to prior cost reporting periods, as provided in § 413.134.

(4) Payments to funds for the donated services of teaching physicians, as provided in § 413.85.

(5) Except as provided in paragraph (f)(2)(iii) of this section for making nominal charge determinations in special situations, graduate medical education costs.

(e) *Reductions in customary charges.* Customary charges are reduced in proportion to the ratio of the aggregate amount actually collected from charge-paying non-Medicare patients to the amount that would have been realized had customary charges been paid, if the provider—

(1) Did not actually impose charges on most of the patients liable for payment for its services on a charge basis; or

(2) Failed to make a reasonable effort to collect those charges.

(f) *Nominal charge determinations.* In determining whether a provider's customary charges equal 60 percent or less of its reasonable costs, the following rules apply:

(1) *General rule.* The determination is based on charges actually billed to charge-paying, non-Medicare patients, and (except for clinical diagnostic laboratory tests that are paid under section 1833(h) of the Act) is made separately for Part A services and Part B services.

(2) *Determination in special situations.* (i) *Charges based on ability to pay.* For providers that have a sliding scale or discounted charges based on patients' ability to pay, the determination—

(A) Is based on charges billed to all charge-paying patients;

(B) Uses the ratio of the sliding scale charges to the provider's full customary charges; and

(C) Applies the ratio to the discounted charges to equate those charges to customary charges.

(ii) *HHA services.* In determining nominal charges for HHAs, all Part A and Part B services, with the exception of DME, are considered together.

(iii) *Graduate medical education.* When making the nominal charge determination, graduate medical education payments (or the provider's reasonable costs for that education, if supported by appropriate data) are included in reasonable costs.

[65 FR 8661, Feb. 22, 2000, as amended at 70 FR 47487, Aug. 12, 2005]

§ 413.17 Cost to related organizations.

(a) *Principle*. Except as provided in paragraph (d) of this section, costs applicable to services, facilities, and supplies furnished to the provider by organizations related to the provider by common ownership or control are includable in the allowable cost of the provider at the cost to the related organization. However, such cost must not exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere.

(b) *Definitions*. (1) *Related to the provider*. Related to the provider means that the provider to a significant extent is associated or affiliated with or has control of or is controlled by the organization furnishing the services, facilities, or supplies.

(2) *Common ownership*. Common ownership exists if an individual or individuals possess significant ownership or equity in the provider and the institution or organization serving the provider.

(3) *Control*. Control exists if an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

(c) *Application*. (1) Individuals and organizations associate with others for various reasons and by various means. Some deem it appropriate to do so to assure a steady flow of supplies or services, to reduce competition, to gain a tax advantage, to extend influence, and for other reasons. These goals may be accomplished by means of ownership or control, by financial assistance, by management assistance, and other ways.

(2) If the provider obtains items of services, facilities, or supplies from an organization, even though it is a separate legal entity, and the organization is owned or controlled by the owner(s) of the provider, in effect the items are obtained from itself. An example would be a corporation building a hospital or a nursing home and then leasing it to another corporation controlled by the owner. Therefore, reimbursable cost should include the costs for these items at the cost to the supplying organization. However, if the price in the open market for comparable services, facilities, or supplies is lower than the cost to the supplier, the allowable cost to the provider may not exceed the market price.

(d) *Exception*. (1) An exception is provided to this general principle if the provider demonstrates by convincing evidence to the satisfaction of the fiscal intermediary (or, if the provider has not nominated a fiscal intermediary, CMS), that—

(i) The supplying organization is a bona fide separate organization;

(ii) A substantial part of its business activity of the type carried on with the provider is transacted with others than the provider and organizations related to the supplier by common ownership or control and there is an open, competitive market for the type of services, facilities, or supplies furnished by the organization;

(iii) The services, facilities, or supplies are those that commonly are obtained by institutions such as the provider from other organizations and are not a basic element of patient care ordinarily furnished directly to patients by such institutions; and

(iv) The charge to the provider is in line with the charge for such services, facilities, or supplies in the open market and no more than the charge made under comparable circumstances to others by the organization for such services, facilities, or supplies.

(2) In such cases, the charge by the supplier to the provider for such services, facilities, or supplies is allowable as cost.

Subpart B—Accounting Records and Reports

§ 413.20 Financial data and reports.

(a) *General*. The principles of cost reimbursement require that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the program. Standardized definitions, accounting, statistics, and reporting practices that are widely accepted in the hospital and related fields are followed. Changes in these practices and systems will not be required in order to determine costs payable under the principles of reimbursement. Essentially the methods of determining costs

payable under Medicare involve making use of data available from the institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services to beneficiaries.

(b) *Frequency of cost reports.* Cost reports are required from providers on an annual basis with reporting periods based on the provider's accounting year. In the interpretation and application of the principles of reimbursement, the fiscal intermediaries will be an important source of consultative assistance to providers and will be available to deal with questions and problems on a day-to-day basis.

(c) *Recordkeeping requirements for new providers.* A newly participating provider of services (as defined in § 400.202 of this chapter) must make available to its selected intermediary for examination its fiscal and other records for the purpose of determining such provider's ongoing recordkeeping capability and inform the intermediary of the date its initial Medicare cost reporting period ends. This examination is intended to assure that—

(1) The provider has an adequate ongoing system for furnishing the records needed to provide accurate cost data and other information capable of verification by qualified auditors and adequate for cost reporting purposes under section 1815 of the Act; and

(2) No financial arrangements exist that will thwart the commitment of the Medicare program to reimburse providers the reasonable cost of services furnished beneficiaries. The data and information to be examined include cost, revenue, statistical, and other information pertinent to reimbursement including, but not limited to, that described in paragraph (d) of this section and in § 413.24.

(d) *Continuing provider recordkeeping requirements.* (1) The provider must furnish such information to the intermediary as may be necessary to—

(i) Assure proper payment by the program, including the extent to which there is any common ownership or control (as described in § 413.17(b)(2) and (3)) between providers or other organizations, and as may be needed to identify the parties responsible for submitting program cost reports;

(ii) Receive program payments; and

(iii) Satisfy program overpayment determinations.

(2) The provider must permit the intermediary to examine such records and documents as are necessary to ascertain information pertinent to the determination of the proper amount of program payments due. These records include, but are not limited to, matters pertaining to—

(i) Provider ownership, organization, and operation;

(ii) Fiscal, medical, and other recordkeeping systems;

(iii) Federal income tax status;

(iv) Asset acquisition, lease, sale, or other action;

(v) Franchise or management arrangements;

(vi) Patient service charge schedules;

(vii) Costs of operation;

(viii) Amounts of income received by source and purpose; and

(ix) Flow of funds and working capital.

(3) The provider, upon request, must furnish the intermediary copies of patient service charge schedules and changes thereto as they are put into effect. The intermediary will evaluate such charge schedules to determine the extent to which they may be used for determining program payment.

(e) *Suspension of program payments to a provider.* If an intermediary determines that a provider does not maintain or no longer maintains adequate records for the determination of reasonable cost under the Medicare program, payments to such provider will be suspended until the intermediary is assured that adequate records are maintained. Before suspending payments to a provider, the intermediary will, in accordance with the provisions in § 405.372(a) of this chapter, send written notice to such provider of its intent to suspend payments. The notice will explain the basis for the intermediary's determination with respect to the provider's records and will identify the provider's recordkeeping deficiencies. The provider must be given the opportunity, in accordance with § 405.372(b) of this chapter, to submit a statement (including any pertinent evidence) as

to why the suspension must not be put into effect.

[51 FR 34793, Sept. 30, 1986, as amended at 61 FR 63749, Dec. 2, 1996]

§ 413.24 Adequate cost data and cost finding.

(a) *Principle.* Providers receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting.

However, if governmental institutions operate on a cash basis of accounting, cost data based on such basis of accounting will be acceptable, subject to appropriate treatment of capital expenditures.

(b) *Definitions.* (1) *Cost finding.* Cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services furnished. It is the determination of these costs by the allocation of direct costs and proration of indirect costs.

(2) *Accrual basis of accounting.* As used in this part, the term *accrual basis of accounting* means that revenue is reported in the period in which it is earned, regardless of when it is collected; and an expense is reported in the period in which it is incurred, regardless of when it is paid. (See § 413.100 regarding limitations on allowable accrued costs in situations in which the related liabilities are not liquidated timely.)

(c) *Adequacy of cost information.* Adequate cost information must be obtained from the provider's records to support payments made for services furnished to beneficiaries. The requirement of adequacy of data implies that the data be accurate and in sufficient detail to accomplish the purposes for which it is intended. Adequate data capable of being audited is consistent with good business concepts and effective and efficient management of any organization, whether it is operated for profit or on a nonprofit basis. It is a reasonable expectation on the part of any agency paying for services on a cost-reimbursement basis. In order to provide the required cost data and not impair comparability, financial and statistical records should be maintained in a manner consistent from one period to another. However, a proper regard for consistency need not preclude a desirable change in accounting procedures if there is reason to effect such change.

(d) *Cost finding methods.* After the close of the accounting period, providers must use one of the following methods of cost finding to determine the actual costs of services furnished during that period. (These provisions do not apply to SNFs that elect and qualify for prospectively determined payment rates under subpart I of this part for cost reporting periods beginning on or after October 1, 1986. For the special rules that are applicable to those SNFs, see § 413.321.) For cost reporting periods beginning after December 31, 1971, providers using the departmental method of cost apportionment must use the step-down method described in paragraph (d)(1) of this section or an ''other method'' described in paragraph (d)(2) of this section. For cost reporting periods beginning after December 31, 1971, providers using the combination method of cost apportionment must use the modified cost finding method described in paragraph (d)(3) of this section. Effective for cost reporting periods beginning on or after October 1, 1980, HHAs not based in hospitals or SNFs must use the step-down method described in paragraph (d)(1) of this section. (HHAs based in hospitals or SNFs must use the method applicable to the parent institution.) However, an HHA not based in a hospital or SNF that received less than $35,000 in Medicare payment for the immediately preceding cost reporting period, and for whom this payment represented less than 50 percent of the total operating cost of the agency, may use a simplified version of the step-down method, as specified in instructions for the cost report issued by CMS.

(1) *Step-down Method.* This method recognizes that services furnished by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue-producing centers as well as by the revenue-producing centers. All costs of nonrevenue-producing

centers are allocated to all centers that they serve, regardless of whether or not these centers produce revenue. The cost of the nonrevenue-producing center serving the greatest number of other centers, while receiving benefits from the least number of centers, is apportioned first. Following the apportionment of the cost of the nonrevenue-producing center, that center will be considered ''closed'' and no further costs are apportioned to that center. This applies even though it may have received some service from a center whose cost is apportioned later. Generally, if two centers furnish services to an equal number of centers while receiving benefits from an equal number, that center which has the greatest amount of expense should be allocated first.

(2) *Other methods.* (i) *The double-apportionment method.* The double-apportionment method may be used by a provider upon approval of the intermediary. This method also recognizes that the nonrevenue-producing departments or centers furnish services to other nonrevenue-producing centers as well as to revenue-producing centers. A preliminary allocation of the costs of non-revenue-producing centers is made. These centers or departments are not ''closed'' after this preliminary allocation. Instead, they remain ''open,'' accumulating a portion of the costs of all other centers from which services are received. Thus, after the first or preliminary allocation, some costs will remain in each center representing services received from other centers. The first or preliminary allocation is followed by a second or final apportionment of expenses involving the allocation of all costs remaining in the nonrevenue-producing functions directly to revenue-producing centers.

(ii) *More sophisticated methods.* A more sophisticated method designed to allocate costs more accurately may be used by the provider upon approval of the intermediary. However, having elected to use the double-apportionment method, the provider may not thereafter use the step-down method without approval of the intermediary. Written request for the approval must be made on a prospective basis and must be submitted before the end of the fourth month of the prospective reporting period. Likewise, once having elected to use a more sophisticated method, the provider may not thereafter use either the double-apportionment or step-down methods without similar request and approval.

(3) *Modified cost finding for providers using the Combination Method for reporting periods beginning after December 31, 1971.* This method differs from the step-down method in that services furnished by nonrevenue-producing departments or centers are allocated directly to revenue-producing departments or centers even though these services may be utilized by other nonrevenue-producing departments or centers. In the application of this method the cost of nonrevenue-producing centers having a common basis of allocation are combined and the total distributed to revenue-producing centers. All nonrevenue-producing centers having significant percentages of cost in relation to total costs will be allocated this way. The combined total costs of remaining nonrevenue-producing costs centers will be allocated to revenue-producing cost centers in the proportion that each bears to total costs, direct and indirect, already allocated. The bases which are to be used and the centers which are to be combined for allocation are not optional but are identified and incorporated in the cost report forms developed for this method. Providers using this method must use the program cost report forms devised for it. Alternative forms may not be used without prior approval by CMS based upon a written request by the provider submitted through the intermediary.

(4) *Temporary method for initial period.* If the provider is unable to use either cost-finding method when it first participates in the program, it may apply to the intermediary for permission to use some other acceptable method that would accurately identify costs by department or center, and appropriately segregate inpatient and outpatient costs. Such other method may be used for cost reports covering periods ending before January 1, 1968.

(5) *Simplified optional reimbursement method for small, rural hospitals with distinct parts for cost reporting periods beginning on or after July 20, 1982.* (i) A

rural hospital with a Medicare-certified distinct part SNF may elect to be reimbursed for services furnished in its hospital general routine service area and distinct part SNF using the reimbursement method specified in § 413.53 for swing-bed hospitals, if it meets the following conditions:

(A) The institution is located in a rural area as defined in § 482.66 of this chapter.

(B) On the first day of the cost reporting period, the hospital and distinct part SNF have fewer than 50 beds in total (with the exception of beds for newborns and beds in intensive care type inpatient units).

(ii) In applying the optional reimbursement method, only those beds located in the hospital general routine service area and in the distinct part SNF certified by Medicare are combined into a single cost center for purposes of cost finding.

(iii) The reasonable cost of the routine extended care services is determined in accordance with § 413.114(c). The reasonable cost of the hospital general routine services is determined in accordance with § 413.53(a)(2).

(iv) The hospital must make its election to use the optional swing-bed reimbursement method in writing to the intermediary before the beginning of the hospital's cost reporting year. The hospital must make any request to revoke the election in writing before the beginning of the affected cost reporting period.

(v) The intermediary must approve requests to terminate use of the optional swing-bed reimbursement method. If a hospital terminates use of this optional method, no further elections may be made by the facility to use the optional method.

(6) *Provider-based entities and departments: Preventing duplication of cost.* In some situations, the main provider in a provider-based complex may purchase services for a provider-based entity or for a department of the provider through a contract for services (for example, a management contract), directly assigning the costs to the provider-based entity or department and reporting the costs directly in the cost center for that entity or department. In any situation in which costs are directly assigned to a cost center, there is a risk of excess cost in that cost center resulting from the directly assigned costs plus a share of overhead improperly allocated to the cost center which duplicates the directly assigned costs. This duplication could result in improper Medicare payment to the provider. Where a provider has purchased services for a provider-based entity or for a provider department, like general service costs of the provider (for example, like costs in the administrative and general cost center) must be separately identified to ensure that they are not improperly allocated to the entity or the department. If the like costs of the main provider cannot be separately identified, the costs of the services purchased through a contract must be reclassified to the main provider and allocated among the main provider's benefiting cost centers.

Example: A provider-based complex is composed of a hospital and a hospital-based rural health clinic (RHC). The hospital furnishes the entirety of its own administrative and general costs internally. The RHC, however, is managed by an independent contractor through a management contract. The management contract provides a full array of administrative and general services, with the exception of patient billing. The hospital directly assigns the costs of the RHC's management contract to the RHC cost center (for example, Form CMS 2552–96, Worksheet A, Line 71). A full allocation of the hospital's administrative and general costs to the RHC cost center would duplicate most of the RHC's administrative and general costs. However, an allocation of the hospital's cost (included in hospital administrative and general costs) of its patient billing function to the RHC would be appropriate. Therefore, the hospital must include the costs of the patient billing function in a separate cost center to be allocated to the benefiting cost centers, including the RHC cost center. The remaining hospital administrative and general costs would be allocated to all cost centers, excluding the RHC cost center. If the hospital is unable to isolate the costs of the patient billing function, the costs of the RHC's management contract must be reclassified to the hospital administrative and general cost center to be allocated among all cost centers, as appropriate.

(7) *Costs of services furnished to freestanding entities.* The costs that a provider incurs to furnish services to freestanding entities with which it is associated are not allowable costs of that

provider. Any costs of services furnished to a free-standing entity must be identified and eliminated from the allowable costs of the servicing provider, to prevent Medicare payment to that provider for those costs. This may be done by including the free-standing entity on the cost report as a nonreimbursable cost center for the purpose of allocating overhead costs to that entity. If this method would not result in an accurate allocation of costs to the entity, the provider must develop detailed work papers showing how the cost of services furnished by the provider to the entity were determined. These costs are removed from the applicable cost centers of the servicing provider.

(e) *Accounting basis.* The cost data submitted must be based on the accrual basis of accounting which is recognized as the most accurate basis for determining costs. However, governmental institutions that operate on a cash basis of accounting may submit cost data on the cash basis subject to appropriate treatment of capital expenditures.

(f) *Cost reports.* For cost reporting purposes, the Medicare program requires each provider of services to submit periodic reports of its operations that generally cover a consecutive 12-month period of the provider's operations. Amended cost reports to revise cost report information that has been previously submitted by a provider may be permitted or required as determined by CMS.

(1) *Cost reports—Terminated providers and changes of ownership.* A provider that voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change of ownership must file a cost report for that period under the program beginning with the first day not included in a previous cost reporting period and ending with the effective date of termination of its provider agreement or change of ownership.

(2) *Due dates for cost reports.* (i) Cost reports are due on or before the last day of the fifth month following the close of the period covered by the report. For cost reports ending on a day other than the last day of the month, cost reports are due 150 days after the last day of the cost reporting period.

(ii) Extensions of the due date for filing a cost report may be granted by the intermediary only when a provider's operations are significantly adversely affected due to extraordinary circumstances over which the provider has no control, such as flood or fire.

(3) *Changes in cost reporting periods.* A provider may change its cost reporting period if a change in ownership is experienced or if the—

(i) Provider requests the change in writing from its intermediary;

(ii) Intermediary receives the request at least 120 days before the close of the new reporting period requested by the provider; and

(iii) Intermediary determines that good cause for the change exists. Good cause would not be found to exist if the effect is to change the initial date that a hospital would be affected by the rate of increase ceiling (see § 413.40), or be paid under the prospective payment systems (see part 412 of this chapter).

(4) *Electronic submission of cost reports.* (i) As used in this paragraph, ''provider'' means a hospital, skilled nursing facility, home health agency, hospice, organ procurement organization, rural health clinic, Federally qualified health clinic, community mental health center, or end-stage renal disease facility.

(ii) Effective for cost reporting periods beginning on or after October 1, 1989 for hospitals, cost reporting periods ending on or after December 31, 1996 for skilled nursing facilities and home health agencies, cost reporting periods ending on or after December 31, 2004 for hospices, and end-stage renal disease facilities, and cost reporting periods ending on or after March 31, 2005 for organ procurement organizations, rural health clinics, Federally qualified health centers, and community mental health centers, a provider is required to submit cost reports in a standardized electronic format. The provider's electronic program must be capable of producing the CMS standardized output file in a form that can be read by the fiscal intermediary's automated system. This electronic file, which must contain the input data required to complete the cost report and

to pass specified edits, must be forwarded to the fiscal intermediary for processing through its system.

(iii) The fiscal intermediary stores the provider's as-filed electronic cost report and may not alter that file for any reason. The fiscal intermediary makes a ''working copy'' of the as-filed electronic cost report to be used, as necessary, throughout the settlement process (that is, desk review, processing audit adjustments, and final settlement). The provider's electronic program must be able to disclose if any changes have been made to the as-filed electronic cost report after acceptance by the intermediary. If the as-filed electronic cost report does not pass all specified edits, the fiscal intermediary must return it to the provider for correction. For purposes of the requirements in paragraph (f)(2) of this section concerning due dates, an electronic cost report is not considered to be filed until it is accepted by the intermediary.

(iv) Effective for cost reporting periods ending on or after September 30, 1994 for hospitals, cost reporting periods ending on or after December 31, 1996 for skilled nursing facilities and home health agencies, cost reporting periods ending on or after December 31, 2004 for hospices and end-stage renal disease facilities, and cost reporting periods ending on or after March 31, 2005 for organ procurement organizations, rural health clinics, Federally qualified health centers, and community mental health centers, a provider must submit a hard copy of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a statement signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. During a transition period (first two cost-reporting periods on or after December 31, 2004 for hospices and end-stage renal disease facilities, and the first two cost-reporting periods on or after March 31, 2005 for organ procurement organizations, rural health clinics, Federally qualified health centers, community mental health centers) providers must submit a hard copy of the completed cost report forms in addition to the electronic file. The following statement must immediately precede the dated signature of the provider's administrator or chief financial officer:

> I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet Statement of Revenue and Expenses prepared by _____ (Provider Name(s) and Number(s)) for the cost reporting period beginning _____ and ending _____ and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

(v) A provider may request a delay or waiver of the electronic submission requirement in paragraph (f)(4)(ii) of this section if this requirement would cause a financial hardship or if the provider qualifies as a low or no Medicare utilization provider. The provider must submit a written request for delay or waiver with necessary supporting documentation to its intermediary no later than 30 days after the end of its cost reporting period. The intermediary reviews the request and forwards it, with a recommendation for approval or denial, to CMS central office within 30 days of receipt of the request. CMS central office either approves or denies the request and notifies the intermediary within 60 days of receipt of the request.

(5) An acceptable cost report submission is defined as follows:

(i) All providers—The provider, must complete and submit the required cost reporting forms, including all necessary signatures. A cost report is rejected for lack of supporting documentation only if it does not include the Provider Cost Reimbursement Questionnaire. Additionally, a cost report for a teaching hospital is rejected for lack of supporting documentation if the cost report does not include a copy of the Intern and Resident Information System diskette.

(ii) For providers that are required to file electronic cost reports—In addition

to the requirements of paragraphs (f)(4) and (f)(5)(i) of this section, the provider must submit its cost reports in an electronic cost report format in conformance with the requirements contained in the Electronic Cost Report (ECR) Specifications Manual (unless the provider has received an exemption from CMS).

(iii) The intermediary makes a determination of acceptability within 30 days of receipt of the provider's cost report. If the cost report is considered unacceptable, the intermediary returns the cost report with a letter explaining the reasons for the rejection. When the cost report is rejected, it is deemed an unacceptable submission and treated as if a report had never been filed.

(g) *Exception from full cost reporting for lack of program utilization.* If a provider does not furnish any covered services to Medicare beneficiaries during a cost reporting period, it is not required to submit a full cost report. It must, however, submit an abbreviated cost report, as prescribed by CMS.

(h) *Waiver of full or simplified cost reporting for low program utilization.* (1) If the provider has had low utilization of covered services by Medicare beneficiaries (as determined by the intermediary) and has received correspondingly low interim payments for the cost reporting period, the intermediary may waive a full cost report or the simplified cost report described in § 413.321 if it decides that it can determine, without a full or simplified report, the reasonable cost of covered services provided during that period.

(2) If a full or simplified cost report is waived, the provider must submit within the same time period required for full or simplified cost reports:

(i) The cost reporting forms prescribed by CMS for this situation; and

(ii) Any other financial and statistical data the intermediary requires.

[51 FR 34793, Sept. 30, 1986, as amended at 57 FR 39829, Sept. 1, 1992; 59 FR 26964, May 25, 1994; 60 FR 33125, 33136, 33143, June 27, 1995; 60 FR 37594, July 21, 1995; 62 FR 31, Jan. 2, 1997; 65 FR 18537, Apr. 7, 2000; 66 FR 59920, Nov. 30, 2001; 68 FR 50721, Aug. 22, 2003; 70 FR 30643, May 27, 2005]

Subpart C—Limits on Cost Reimbursement

§ 413.30 Limitations on payable costs.

(a) *Introduction*—(1) *Scope.* This section implements section 1861(v)(1)(A) of the Act by setting forth the general rules under which CMS may establish limits on SNF and HHA costs recognized as reasonable in determining Medicare program payments. It also sets forth rules governing exemptions and exceptions to limits established under this section that CMS may make as appropriate in considering special needs or situations of particular providers.

(2) *General principle.* Reimbursable provider costs may not exceed the costs CMS estimates to be necessary for the efficient delivery of needed health care services. CMS may establish estimated cost limits for direct or indirect overall costs or for costs of specific services or groups of services. CMS imposes these limits prospectively and may calculate them on a per admission, per discharge, per diem, per visit, or other basis.

(b) *Procedure for establishing limits.* (1) In establishing limits under this section, CMS may classify SNFs and HHAs by factors that CMS finds appropriate and practical, including the following:

(i) Type of services furnished.

(ii) Geographical area where services are furnished, allowing for grouping of noncontiguous areas having similar demographic and economic characteristics.

(iii) Size of institution.

(iv) Nature and mix of services furnished.

(v) Type and mix of patients treated.

(2) CMS bases its estimates of the costs necessary for efficient delivery of health services on cost reports or other data providing indicators of current costs. CMS adjusts current and past period data to arrive at estimated costs for the prospective periods to which limits are applied.

(3) Before the beginning of a cost period to which revised limits will be applied, CMS publishes a notice in the FEDERAL REGISTER, establishing cost limits and explaining the basis on which they are calculated.

(4) In establishing limits under paragraph (b)(1) of this section, CMS may find it inappropriate to apply particular limits to a class of SNFs or HHAs due to the characteristics of the SNF or HHA class, the data on which CMS bases those limits, or the method by which CMS determines the limits. In these cases, CMS may exclude that class of SNFs or HHAs from the limits, explaining the basis of the exclusion in the notice setting forth the limits for the appropriate cost reporting periods.

(c) *Requests regarding applicability of cost limits.* For cost reporting periods beginning before July 1, 1998, a SNF may request an exception or exemption to the cost limits imposed under this section. An HHA may request only an exception to the cost limits. The SNF or HHA must make its request to its fiscal intermediary within 180 days of the date on the intermediary's notice of program reimbursement.

(1) *Home health agencies.* The intermediary makes a recommendation on the HHA's request to CMS, which makes the decision. CMS responds to the request within 180 days from the date CMS receives the request from the intermediary. The intermediary notifies the HHA of CMS's decision. The time required by CMS to review the request is considered good cause for the granting of an extension of the time limit for the HHA to apply for a PRRB review, as specified in § 405.1841 of this chapter. CMS's decision is subject to review under subpart R of part 405 of this chapter.

(2) *Skilled nursing facility exception.* The intermediary makes the final determination on the SNF's exception request and notifies the SNF of its determination within 90 days from the date that the intermediary receives the request from the SNF. If the intermediary determines that the SNF did not provide adequate documentation from which a proper determination can be made, the intermediary notifies the SNF that the request is denied. The intermediary also notifies the SNF that it has 45 days from the date on the intermediary's denial letter to submit a new exception request with the complete documentation and that otherwise, the denial is the final determination. The time required by the intermediary to review the request is considered good cause for the granting of an extension of the time limit for the SNF to apply for a PRRB review, as specified in § 405.1841 of this chapter. The intermediary's determination is subject to review under subpart R of part 405 of this chapter.

(d) *Exemptions.* Exemptions from the limits imposed under this section may be granted to a new SNF with cost reporting periods beginning before July 1, 1998 as stated in § 413.1(g)(1). The intermediary makes a recommendation on the provider's request to CMS, which makes the decision. A new SNF is a provider of inpatient services that has operated as a SNF (or the equivalent) for which it is certified for Medicare, under present and previous ownership, for less than 3 full years. An exemption granted under this paragraph expires at the end of the SNF's first cost reporting period beginning at least 2 years after the provider accepts its first inpatient.

(e) *Exceptions.* Limits established under this section may be adjusted upward for a SNF or HHA under the circumstances specified in paragraphs (e)(1) through (e)(5) of this section. An adjustment is made only to the extent that the costs are reasonable, attributable to the circumstances specified, separately identified by the SNF or HHA, and verified by the intermediary.

(1) *Atypical services.* The SNF or HHA can show that the—

(i) Actual cost of services furnished by a SNF or HHA exceeds the applicable limit because the services are atypical in nature and scope, compared to the services generally furnished by SNFs or HHAs similarly classified; and

(ii) Atypical services are furnished because of the special needs of the patients treated and are necessary in the efficient delivery of needed health care.

(2) *Extraordinary circumstances.* The SNF or HHA can show that it incurred higher costs due to extraordinary circumstances beyond its control. These circumstances include, but are not limited to, strikes, fire, earthquake, flood, or other unusual occurrences with substantial cost effects.

(3) *Areas with fluctuating populations.* The SNF meets the following conditions:

(i) Is located in an area (for example, a resort area) that has a population that varies significantly during the year.

(ii) Is furnishing similar services in an area for which the appropriate health planning agency has determined does not have a surplus of beds or similar services and has certified that the beds or similar services furnished by the SNF are necessary.

(iii) Meets occupancy or capacity standards established by the Secretary.

(4) *Medical and paramedical education.* The SNF or HHA can demonstrate that, if compared to other SNFs or HHAs in its group, it incurs increased costs for services covered by limits under this section because of its operation of an approved education program specified in § 413.85.

(5) *Unusual labor costs.* The SNF or HHA has a percentage of labor costs that varies more than 10 percent from that included in the promulgation of the limits.

(f) *Operational review.* Any SNF or HHA that applies for an exception to the limits established under paragraph (e) of this section must agree to an operational review at the discretion of CMS. The findings from this review may be the basis for recommendations for improvements in the efficiency and economy of the SNF's or the HHA's operations. If recommendations are made, any future exceptions are contingent on the SNF's or HHA's implementation of these recommendations.

[64 FR 42612, Aug. 5, 1999; 65 FR 60104, Oct. 10, 2000, as amended at 67 FR 48802, July 26, 2002]

§ 413.35 Limitations on coverage of costs: Charges to beneficiaries if cost limits are applied to services.

(a) *Principle.* A provider of services that customarily furnishes an individual items or services that are more expensive than the items or services determined to be necessary in the efficient delivery of needed health services described in § 413.30, may charge an individual entitled to benefits under Medicare for such more expensive items or services even though not requested by the individual. The charge, however, may not exceed the amount by which the cost of (or, if less, the customary charges for) such more expensive items or services furnished by such provider in the second cost reporting period immediately preceding the cost reporting period in which such charges are imposed exceeds the applicable limit imposed under the provisions of § 413.30. This charge may be made only if—

(1) The intermediary determines that the charges have been calculated properly in accordance with the provisions of this section;

(2) The services are not emergency services as defined in paragraph (d) of this section;

(3) The admitting physician has no direct or indirect financial interest in such provider;

(4) CMS has provided notice to the public through notice in a newspaper of general circulation servicing the provider's locality and such other notice as the Secretary may require, of any charges the provider is authorized to impose on individuals entitled to benefits under Medicare on account of costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare; and

(5) The provider has, in the manner described in paragraph (e) of this section, identified such charges to such individual or person acting on his behalf as charges to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare.

(b) *Provider request to charge beneficiaries for costs in excess of limits.* (1) If a provider's actual costs (or, if less, the customary charges) in the second preceding cost period exceed the prospective limits established for such costs, the intermediary will, at the provider's request, validate in advance the charges that may be made to the beneficiaries for the excess.

(2) If a provider does not have a second preceding cost period and is a new provider as defined in § 413.30(e), the provider, subject to validation by the intermediary, will estimate the current cost of the service to which a limit is being applied. Such amount will be adjusted to an amount equivalent to costs in the second preceding year by use of a factor to be developed based on estimates of cost increases during the

preceding two years and published by SSA or CMS. The amount thus derived will be used in lieu of the second preceding cost period amount in determining the charge to the beneficiary.

(3) To obtain consideration of such a request, the provider must submit to the intermediary a statement indicating the chagre for which it is seeking validation and providing the data and method used to determine the amount. Such statement should include the—

(i) Provider's name and number;

(ii) Identity of class and prospective cost limit for the class in which the provider has been included;

(iii) Amount of charge and cost period in which the charge is to be imposed;

(iv) Cost and customary charge for items and services furnished to beneficiaries; and

(v) Cost period ending date of the second reporting period immediately preceding the cost period in which the charge is to be imposed. The intermediary may request such additional information as it finds necessary with respect to the request.

(c) *Provider charges*—(1) *Establishing the charges*. If the actual cost incurred (or, if less, the customary charges) in the prior period determined under paragraph (a) of this section exceeds the limits applicable to the pertinent period, the provider may charge the beneficiary to the extent costs in the second preceding cost reporting period (or the equivalent when there is no second preceding period) exceed the current cost limits. (Data from the most recently submitted appropriate cost report will be used in determining the actual cost.) For example, if a limit of $58 per day is applied to the cost of general routine services for the provider's cost reporting period starting in calendar year 1975 and if the provider's actual general routine cost in the second preceding reporting period, that is, the reporting period starting in calendar year 1973, was $60 per day, the provider (after first having obtained intermediary validation and subject to the considerations and requirements specified in paragraph (a) of this section) may charge Medicare Part A beneficiaries up to $2 per day for general routine services.

(2) *Adjusting cost*. Program reimbursement for the costs to which limits imposed under § 413.30 are applied in any cost reporting period will not exceed the lesser of the provider's actual cost or the limits imposed under § 413.30. If program reimbursement for items or services to which such limits are applied plus the charges to beneficiaries for such items or services imposed under this section exceed the provider's actual cost for such items or services, program payment to the provider will be reduced to the extent program payment plus charges to the beneficiaries exceed actual cost. If the provider's actual cost for general routine services in 1975 was $57,000, the cost limit was $58,000, and billed charges to Medicare Part A beneficiaries were $2,000, the provider would receive $55,000 from the program ($57,000 actual cost minus the $2,000 in charges to the beneficiaries).

(d) *Definition of emergency services*. For purposes of paragraph (a)(2) of this section, emergency services are those hospital services that are necessary to prevent the death or serious impairment of the health of the individual, and which, because of the threat to the life or health of the individual, necessitate the use of the most accessible hospital (as determined under § 424.106 of this chapter) available and equipped to furnish such services. If an individual has been admitted to such hospital as an inpatient because of an emergency, the emergency will be deemed to continue until it is safe from a medical standpoint to move the individual to another hospital or other institution or to discharge him.

(e) *Identification of charges to individual*. For purposes of paragraph (a)(5) of this section, a provider must give or send to the individual or his representative, a schedule of all items and services that the individual might need and for which the provider imposes charges under this section, and the charge for each. Such schedule must specify that the charges are necessary to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare and include such other information as CMS considers necessary to

protect the individual's rights under this section. The provider, in arranging for the individual's admission, first service, or start of care, must give or send this schedule to the individual or his representative when arrangements are being made for such services or if this is not feasible, as soon thereafter as is practicable but no later than at the initiation of services.

[51 FR 34793, Sept. 30, 1986, as amended at 53 FR 6648, Mar. 20, 1988; 60 FR 45849, Sept. 1, 1995]

§ 413.40 Ceiling on the rate of increase in hospital inpatient costs.

(a) *Introduction*—(1) *Scope*. This section implements section 1886(b) of the Act, establishing a ceiling on the rate of increase in operating costs per case for hospital inpatient services furnished to Medicare beneficiaries that will be recognized as reasonable for purposes of determining the amount of Medicare payment. This rate-of-increase ceiling applies to hospital cost reporting periods beginning on or after October 1, 1982. This section also sets forth rules governing exemptions from and adjustments to the ceiling.

(2) *Applicability*. (i) This section is not applicable to—

(A) Hospitals reimbursed in accordance with section 1814(b)(3) of the Act or under State reimbursement control systems that have been approved under section 1886(c) of the Act and subpart C of part 403 of this chapter; or

(B) Hospitals that are paid under the prospective payment systems for inpatient hospital services in accordance with section 1886 (d) and (g) of the Act and part 412 of this chapter.

(C) Psychiatric hospitals and psychiatric units that are paid under the prospective payment system for inpatient psychiatric facilities described in subpart N of part 412 of this chapter for cost reporting periods beginning on or after January 1, 2005.

(D) Rehabilitation hospitals and rehabilitation units that are paid under the prospective payment system for inpatient hospital services in accordance with section 1886(j) of the Act and subpart P of part 412 of this subchapter for cost reporting periods beginning on or after January 1, 2002.

(E) Long-term care hospitals, as defined in section 1886(d)(1)(B)(iv) of the Act, that are paid based on 100 percent of the Federal prospective payment rate for inpatient hospital services in accordance with section 123 of Public Law 106–113 and section 307 of Public Law 106–554 and § 412.533(b) and (c) of subpart O of Part 412 of this subchapter for cost reporting periods beginning on or after October 1, 2002.

(ii) For cost reporting periods beginning on or after October 1, 1983, this section applies to—

(A) Hospitals excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter;

(B) Psychiatric and rehabilitation units excluded from the prospective payment systems, as specified in § 412.1(a)(1) of this chapter and in accordance with § 412.25 through § 412.30 of this chapter, except as limited by paragraphs (a)(2)(iii) and (a)(2)(iv) of this section with respect to psychiatric and rehabilitation hospitals and psychiatric and rehabilitation units as specified in § 412.22, § 412.23, § 412.25, § 412.27, § 412.29 and § 412.30 of this chapter.

(C) Long-term care hospitals excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter and in accordance with § 412.23 of this subchapter, except as limited by paragraph (a)(2)(v) of this section with respect to long-term care hospitals specified in § 412.23(e) of this subchapter.

(iii) For cost reporting periods beginning on or after October 1, 1983 and before January 1, 2005 this section applies to psychiatric hospitals and psychiatric units that are excluded from the prospective payment systems as specified in § 412.1(a)(1) of this chapter and paid under the prospective payment system as specified in § 412.1(a)(2) of this chapter.

(iv) For cost reporting periods beginning on or after October 1, 1983 and before January 1, 2002, this section applies to rehabilitation hospitals and rehabilitation units that are excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter.

(v) For cost reporting periods beginning on or after October 1, 1983 and before October 1, 2002, this section applies to long-term care hospitals that are excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter. For cost reporting periods beginning on or after October 1, 2002, and before October 1, 2006, this section also applies to long-term care hospitals, subject to paragraph (a)(2)(i)(D) of this section.

(3) *Definitions.* As used in this section—

Ceiling is the aggregate upper limit on the amount of a hospital's net Medicare inpatient operating costs that the program will recognize for payment purposes. For each cost reporting period, the ceiling is determined by multiplying the updated target amount, as defined in this paragraph, for that period by the number of Medicare discharges during that period. For a hospital-within-a-hospital, as described in § 412.22(e) of this chapter, the number of Medicare discharges in a cost reporting period does not include discharges of a patient to another hospital in the same building on or on the same campus, if—

(A) The patient is subsequently readmitted to the hospital-within-a-hospital directly from the other hospital; and

(B) The hospital-within-a-hospital has discharged to the other hospital and subsequently readmitted more than 5 percent (that is, in excess of 5.0 percent) of the total number of Medicare inpatients discharged from the hospital-within-a-hospital in that cost reporting period.

Date of discharge is the earliest of the following dates:

(A) The date the patient has exhausted Medicare Part A hospital inpatient benefits (including the election to use lifetime reserve days) during his or her spell of illness.

(B) The date the patient is formally released as specified in § 412.4(a)(1) of this chapter.

(C) The date the patient is transferred to another facility.

(D) The date the patient dies.

Market basket index is CMS's projection of the annual percentage increase in hospital inpatient operating costs. The market basket index is a wage and price index that incorporates weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in the most common categories of hospital inpatient operating costs subject to the ceiling, as described in paragraph (c)(1) of this section.

Net inpatient operating costs include the costs of certain preadmission services as specified in § 413.40(c)(2), the costs of routine services, ancillary services, and intensive care services (as defined in § 413.53(b)) incurred by a hospital in furnishing covered inpatient services to Medicare beneficiaries. Net inpatient operating costs exclude capital-related costs as described in § 413.130, the costs of approved medical education programs as described in §§ 413.75 through 413.83 and 413.85, and heart, kidney, and liver acquisition costs incurred by approved transplantation centers. These costs are identified and excluded from inpatient operating costs before the application of the ceiling.

Rate-of-increase percentage is the percentage by which each hospital's target amount from the preceding Federal fiscal year is increased.

Target amount is the per discharge (case) limitation, derived from the hospital's allowable net Medicare inpatient operating costs in the hospital's base year, and updated for each subsequent hospital cost reporting period by the appropriate annual rate-of-increase percentage.

Update adjustment percentage is the percentage by which a hospital's allowable inpatient operating service costs for the 12-month cost reporting period beginning in Federal fiscal year 1990 exceeds the hospital's ceiling for that period.

Update factor is the decimal equivalent of the rate-of-increase percentage. The update factor is the value by which a hospital's target amount for the preceding year is multiplied in order to determine the target amount for the following year. For example, if the rate-of-increase percentage for a year is 2.7 percent, the update factor for that year is 1.027.

(b) *Cost reporting periods subject to the rate-of-increase ceiling.* (1) *Base period.* Each hospital's target amount is based

on its allowable net inpatient operating costs per case from the cost reporting period of at least 12 months immediately preceding the first cost reporting period subject to the rate-of-increase ceiling established under this section. If the immediately preceding cost reporting period is a short reporting period (fewer than 12 months), the first period of at least 12 months subsequent to that short period is the base period.

(i) The target amount established under this provision remains applicable to a hospital or excluded hospital unit, as described in §§ 412.25 through 412.30 of this chapter, despite intervening cost reporting periods during which the hospital or excluded hospital unit is not subject to the ceiling as a result of other provisions of the law or regulations, or nonparticipation in the Medicare program, unless the hospital or excluded hospital unit qualifies as a new hospital or excluded part hospital unit under the provisions of paragraph (f) of this section.

(ii) The base period for a newly established excluded unit is the first cost reporting period of at least 12 months following the unit's certification to participate in the Medicare program.

(iii) When the operational structure of a hospital or unit changes (that is, a freestanding hospital becomes an excluded unit or an excluded unit becomes a freestanding hospital, or an entity of a multicampus hospital becomes a newly created hospital or unit or a hospital or unit becomes a part of a multicampus hospital), the base period for the hospital or unit that changed its operational structure is the first cost reporting period of at least 12 months effective with the revised Medicare certification classification.

(iv) *Request for rebased target amount for the cost reporting period beginning on or after October 1, 1997 and on or before September 30, 1998.* Except for qualified long-term care hospitals as defined in paragraph (b)(1)(v) of this section, each hospital or unit under present or previous ownership that received payment under section 1886(b) of the Act during cost reporting periods beginning before October 1, 1990, may submit a request to its fiscal intermediary to rebase its target amount. The request must be received by the fiscal intermediary by the later of November 1, 1997 or 60 days before the beginning of its cost reporting period beginning during fiscal year 1998. The rebased target amount for the cost reporting period beginning during fiscal year 1998 is determined as follows:

(A) Determine the hospital's inpatient operating costs per case for each of the five most recent settled cost reports as of August 5, 1997.

(B) For each of the five cost reports, update the operating costs per case by the applicable update factors up to the hospital's cost reporting period beginning during FY 1998.

(C) Exclude the highest and lowest of the five updated amounts determined under paragraph (b)(1)(iv)(B) of this section.

(D) Compute the average for the remaining three updated amounts for operating cost per case.

(v) *Request by qualified long-term care hospital.* A qualified long-term care hospital may file a request to its fiscal intermediary for a rebased FY 1998 target amount. The request must be received by the fiscal intermediary by the later of November 1, 1997 or 60 days before the beginning of its cost reporting period beginning during fiscal year 1998. The rebased FY 1998 target amount is the hospital's FY 1996 inpatient operating costs updated to FY 1997. A qualified long-term care hospital means a long-term care hospital that meets the following two conditions for its two most recent settled cost reports as of August 5, 1997:

(A) Its Medicare inpatient operating costs exceed 115 percent of the ceiling.

(B) The hospital would have had a disproportionate patient percentage (as defined in § 412.106) equal to or greater than 70 percent if it were a prospective payment hospital.

(2) *Periods subject to the ceiling.* The ceiling established under this section applies to all cost reporting periods that—

(i) Begin on or after October 1, 1982; and

(ii) Immediately follow the base period established under paragraph (b)(1) of this section unless the exception in

paragraph (b)(3) of this section is applicable.

(3) *Periods of other than 12 months.* The ceiling established under this section does not apply to cost reporting periods of fewer than 12 months that occur in conjunction with a change in operation of the facility, as defined in paragraph (b)(1)(iii) of this section, as a result of changes in ownership, merger, or consolidation. However, the ceiling applies to cost reporting periods of fewer than 12 months that result solely from the approval of a hospital's request for a change in accounting cycle, as specified in § 413.24(f)(3).

(c) *Costs subject to the ceiling*—(1) *Applicability.* The ceiling established under this section applies to net operating costs incurred by a hospital in furnishing inpatient hospital services to Medicare beneficiaries.

(2) Preadmission services otherwise payable under Medicare Part B furnished to a beneficiary during the calendar day immediately preceding the date of the beneficiary's admission to the hospital that meet the following conditions:

(i) The services are furnished by the hospital or any entity wholly owned or operated by the hospital. An entity is wholly owned by the hospital if the hospital is the sole owner of the entity. An entity is wholly operated by a hospital if the hospital has exclusive responsibility for conducting and overseeing the entity's routine perations, regardless of whether the hospital also has policymaking authority over the entity.

(ii) For services furnished after January 1, 1991, the services are diagnostic (including clinical diagnostic laboratory tests).

(iii) For services furnished on or after October 1, 1991, the services are furnished in connection with the principal diagnosis that requires the beneficiary to be admitted as an inpatient and are not the following:

(A) Ambulance services.

(B) Maintenance renal dialysis.

(3) *Rate-of-increase percentages and update factors.* The applicable rate-of-increase percentages and update factors are determined as follows:

(i) *Federal fiscal year 1986.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1985 and before September 30, 1986 is five twenty-fourths of one percent, and the update factor is 1.00208333. For purposes of determining the target amount for cost reporting periods beginning on or after October 1, 1986, the applicable percentage increase for cost reporting periods beginning during Federal fiscal year 1986 is deemed to have been one-half percent, and the update factor is 1.005.

(ii) *Federal fiscal year 1987.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1986 and before September 30, 1987 is 1.15 percent; the update factor is 1.0115.

(iii) *Federal fiscal year 1988.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1987 and before October 1, 1988 is 2.3238 percent; the update factor is 1.023238. For purposes of updating the target amount for cost reporting periods beginning on or after October 1, 1988, the rate-of-increase percentage for cost reporting periods beginning during FY 1988 is deemed to have been 2.7 percent; the update factor is deemed to have been 1.027.

(iv) *Federal fiscal year 1989 through Federal fiscal year 1993.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1988, and before October 1, 1993, is the percentage increase projected by the hospital market basket index (as defined in paragraph (a)(3) of this section).

(v) *Federal fiscal year 1994 through Federal fiscal year 1997.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1993, and before October 1, 1998, is the market basket percentage increase minus the lesser of, 1 percentage point, or the percentage point difference between 10 percent and the hospital's ''update adjustment percentage'' (as defined in paragraph (a)(3) of this section); for hospitals with an ''update adjustment percentage'' of at least 10 percent, the applicable rate-of-increase percentage is the market basket percentage increase. The ''update adjustment percentage'' is increased in each Federal fiscal year by the sum of

the hospital's applicable reductions applied to the market basket percentage increase for previous Federal fiscal years.

(vi) *Federal fiscal year 1998*. The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1997 is 0 percent.

(vii) *Federal fiscal year 1999 through Federal fiscal year 2002*. The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1998, and before October 1, 2002, based n data from the most recent available cost report, is:

(A) The percentage increase in the market basket, if inpatient operating costs are equal to or exceed the ceiling amount by 10 percent or more of the ceiling.

(B) The percentage increase in the market basket minus .25 percentage points for each percentage point by which inpatient operating costs are less than 10 percent over the ceiling (but not less than 0), if inpatient operating costs exceed the ceiling by less than 10 percent of the ceiling.

(C) The greater of the percentage increase in the market basket minus 2.5 percentage points or 0 percent, if inpatient operating costs are equal to or less than the ceiling but greater than 66.7 percent of the ceiling.

(D) 0 percent, if inpatient operating costs do not exceed 66.7 percent of the ceiling.

(viii) *Federal fiscal year 2003 and following*. The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 2002, is the percentage increase projected by the hospital market basket index.

(4) *Target amounts*. The intermediary will establish a target amount for each hospital. The target amount for a cost reporting period is determined as follows:

(i) Except as provided in paragraph (c)(4)(iv) of this section, and subject to the provisions of paragraph (c)(4)(iii) of this section, for the first cost reporting period to which this ceiling applies, the target amount equals the hospital's allowable net inpatient operating costs per case for the hospital's base period increased by the update factor for the subject period.

(ii) Subject to the provisions of paragraph (c)(4)(iii) of this section, for subsequent cost reporting periods, the target amount equals the hospital's target amount for the previous cost reporting period increased by the update factor for the subject cost reporting period, unless the provisions of paragraph (c)(5)(ii) of this section apply.

(iii) For cost reporting periods beginning on or after October 1, 1997 through September 30, 2002, in the case of a psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital, the target amount is the lower of the amounts specified in paragraph (c)(4)(iii)(A) or paragraph (c)(4)(iii)(B) of this section.

(A) The hospital-specific target amount.

(*1*) In the case of all hospitals and units, except long-term care hospitals for cost reporting periods beginning during FY 2001, the hospital-specific target amount is the net allowable costs in a base period increased by the applicable update factors .

(*2*) In the case of long-term care hospitals, for cost reporting periods beginning during FY 2001, the hospital-specific target amount is the net allowable costs in a base period increased by the applicable update factors multiplied by 1.25.

(B) One of the following for the applicable cost reporting period—

(*1*) For cost reporting periods beginning during fiscal year 1998, the 75th percentile of target amounts for hospitals in the same class (psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital) for cost reporting periods ending during FY 1996, increased by the applicable market basket percentage up to the first cost reporting period beginning on or after October 1, 1997.

(*2*) For cost reporting periods beginning during fiscal year 1999, the amount determined under paragraph (c)(4)(iii)(B)(*1*) of this section, increased by the market basket percentage up through the subject period, subject to the provisions of paragraph (c)(4)(iv) of this section.

(*3*) For cost reporting periods beginning during fiscal year 2000—

(*i*) The labor-related portion and the nonlabor-related portion of the wage-

neutralized 75th percentile of target amounts for hospitals in the same class (psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital) for cost reporting periods ending during FY 1996, are increased by the applicable market basket percentage up to the first cost reporting period beginning on or after October 1, 1999.

(*ii*) The labor-related portion of the wage-neutralized 75th percentile target amounts under paragraph (c)(4)(iii)(B)(*4*)(*i*) of this section is wage adjusted by multiplying it by the hospital's FY 2000 hospital inpatient prospective payment system wage index.

(*iii*) The wage-adjusted 75th percentile target amounts for hospitals in the same class is determined by adding the nonlabor-related portion of the wage-neutralized 75th percentile target amounts under paragraph (c)(4)(iii)(B)(*3*)(*i*) of this section and the hospital's wage-adjusted labor-related portion of the wage-neutralized 75th percentile target amounts determined under paragraph (c)(4)(iii)(B)(*3*)(*ii*) of this section, subject to the provisions of paragraph (c)(4)(iv) of this section.

(*4*) For cost reporting periods beginning during fiscal years 2001 and 2002—

(*i*) The amounts determined under paragraph (c)(4)(iii)(B)(3)(*i*) of this section are: increased by the market basket percentage up through the subject period; or in the case of a long-term care hospital for cost reporting periods beginning during FY 2001, the amounts determined under paragraph (c)(4)(iii)(B)(*3*)(*i*) of this section, increased by the market basket percentage up through the subject period and further increased by 2 percent.

(*ii*) The labor-related portion of the wage-neutralized 75th percentile target amounts under paragraph (c)(4)(iii)(B)(*4*)(*i*) of this section is wage-adjusted by multiplying by the hospital's FY 2001 hospital inpatient prospective payment system wage index, for cost reporting periods beginning during fiscal year 2001 and the hospital's FY 2002 hospital inpatient prospective payment system wage index for cost reporting periods beginning during fiscal year 2002.

(*iii*) The wage-adjusted 75th percentile target amounts for hospitals in the same class are determined by adding the nonlabor-related portion of the wage-neutralized 75th percentile target amounts under paragraph (c)(4)(iii)(B)(*4*)(*i*) of this section and the hospital's wage-adjusted labor-related portion of the wage-neutralized 75th percentile target amounts determined under paragraph (c)(4)(iii)(B)(*4*)(*ii*) of this section, subject to the provisions of paragraph (c)(4)(iv) of this section.

(iv) For purposes of the limits on target amounts established under paragraph (c)(4)(iii) of this section, each hospital or unit that qualifies for exclusion as a member of only one class of excluded facility (psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital) will be subject to the limit applicable to that class. If a hospital or unit qualifies to be classified in more than one way under the exclusion criteria in subpart B of part 412 of this chapter, the hospital's or unit's target amount may not exceed the lowest applicable limit.

(v) In the case of a hospital that received payments under paragraph (f)(2)(ii) of this section as a newly created hospital or unit, to determine the hospital's target amount for the hospital's third 12-month cost reporting period, the payment amount determined under paragraph (f)(2)(ii)(A) of this section for the preceding cost reporting period is updated to the third cost reporting period.

(5) *Applicable update factor*. (i) The applicable update factor is derived from the prospectively determined rate-of-increase percentage published by CMS. The update factor for each Federal fiscal year is applied prospectively to the target amount for each cost reporting period beginning during the Federal fiscal year.

(ii) In the case of cost reporting periods of less than 12 months, the target amount determined for a hospital's first cost reporting period beginning in a Federal fiscal year applies to subsequent periods beginning in the same Federal fiscal year.

(d) *Application of the target amount in determining the amount of payment*. (1) *General process*. (i) At the end of each cost reporting period subject to this section, the hospital's intermediary

will compare a hospital's allowable net inpatient operating costs with that hospital's ceiling (as defined in paragraph (a)(3) of this section) for that period.

(ii) The hospital's actual allowable costs will be determined without regard to the lesser of cost or charges provisions of § 413.13, and in accordance with the provisions of paragraphs (d)(2) or (d)(3) of this section, as applicable.

(2) *Net inpatient operating costs are less than or equal to the ceiling.*(i) For cost reporting periods beginning on or after October 1, 1997, if a hospital's allowable net inpatient operating costs do not exceed the hospital's ceiling, payment to the hospital will be determined on the basis of the lower of the—

(A) Net inpatient operating costs plus 15 percent of the difference between inpatient operating costs and the ceiling; or

(B) Net inpatient operating costs plus 2 percent of the ceiling.

(ii) For psychiatric hospitals and units, for cost reporting periods beginning on or after October 1, 2000 and before October 1, 2001, if a hospital's allowable net inpatient operating costs do not exceed the hospital's ceiling, payment to the hospital will be determined on the basis of the lower of the—

(A) Net inpatient operating costs plus 15 percent of the difference between inpatient operating costs and the ceiling; or

(B) Net inpatient costs plus 3 percent of the ceiling.

(3) *Net inpatient operating costs are greater than the ceiling.* For cost reporting periods beginning on or after October 1, 1997—

(i) If a hospital's allowable net inpatient operating costs do not exceed 110 percent of the ceiling (or the adjusted ceiling, if applicable), payment will be the ceiling (or the adjusted ceiling, if applicable);

(ii) If a hospital's allowable net inpatient operating costs are greater than 110 percent of the ceiling (or the adjusted ceiling, if applicable), payment will be the ceiling (or the adjusted ceiling, if applicable) plus the lesser of:

(A) 50 percent of the allowable net inpatient operating costs in excess of 110 percent of the ceiling (or the adjusted ceiling, if applicable); or

(B) 10 percent of the ceiling (or the adjusted ceiling, if applicable).

(4) *Continuous improvement bonus payments.* (i) For cost reporting periods beginning on or after October 1, 1997, eligible hospitals (as defined in paragraph (d)(5) of this section) receive payments in addition to those in paragraph (d)(2) of this section, as applicable. These payments are equal to the lesser of—

(A) 50 percent of the amount by which the operating costs are less than the expected costs for the period; or

(B) 1 percent of the ceiling.

(ii) For cost reporting periods beginning on or after October 1, 2000, and before September 30, 2001, eligible psychiatric hospitals and units and long-term care hospitals (as defined in paragraph (d)(5) of this section) receive payments in addition to those in paragraph (d)(2) of this section, as applicable. These payments are equal to the lesser of—

(A) 50 percent of the amount by which the operating costs are less than the expected costs for the period; or

(B) 1.5 percent of the ceiling.

(iii) For cost reporting periods beginning on or after October 1, 2001, and before September 30, 2002, eligible psychiatric hospitals and units and long-term care hospitals receive payments in addition to those in paragraph (d)(5) of this section, as applicable. These payments are equal to the lesser of—

(A) 50 percent of the amount by which the operating costs are less than the expected costs for the periods; or

(B) 2 percent of the ceiling.

(5) *Eligibility requirements for continuous improvement bonus payments.* To qualify, a hospital must have been paid as a prospective payment excluded hospital for at least three full cost reporting periods prior to the applicable period, and the hospital's operating costs per discharge for the period must be less than the least of the following:

(i) The hospital's target amount.

(ii) The hospital's trended costs.

(A) For a hospital for which its cost reporting period ending during fiscal year 1996 was its third or subsequent full cost reporting period, trended costs are the lesser of the allowable inpatient operating costs per discharge or

the target amount for the cost reporting period ending in fiscal year 1996, increased in a compounded manner for each succeeding fiscal year by the market basket percentage increase;

(B) For all other hospitals, trended costs are the allowable inpatient operating costs per discharge for its third full cost reporting period increased in a compounded manner for each succeeding fiscal year by the market basket increase.

(iii) The hospital's expected costs. The hospital's expected costs are the lesser of its allowable inpatient operating costs per discharge or the target amount for the previous cost reporting period, updated by the market basket percentage increase for the fiscal year.

(e) *Hospital requests regarding adjustments to the payment allowed under the rate-of-increase ceiling.* (1) *Timing of application.* A hospital may request an adjustment to the rate-of-increase ceiling imposed under this section. The hospital's request must be received by the hospital's fiscal intermediary no later than 180 days after the date on the intermediary's initial notice of amount of program reimbursement (NPR) for the cost reporting period for which the hospital requests an adjustment.

(2) *Intermediary recommendation.* Unless CMS has authorized the intermediary to make the decision, the intermediary makes a recommendation on the hospital's request to CMS, which makes the decision. CMS issues a decision to the intermediary no later than 180 days after receipt of the completed application and the intermediary's recommendation.

(3) *Intermediary decision.* If CMS has authorized the intermediary to make the decision, the intermediary issues a decision no later than 180 days after receipt of the completed application.

(4) *Notification and review.* (i) The intermediary notifies the hospital of the decision, including a full explanation of the grounds for the decision. A decision issued under paragraph (e)(2) or (e)(3) of this section is considered final unless the hospital submits additional information and requests a review of the decision no later than 180 days after the date on the intermediary's notice of the decision.

(ii) The final decision is subject to review under the provider reimbursement determination and appeal procedures in subpart R of part 405 of this chapter, provided the hospital has received an NPR for the cost reporting period in question, and the NPR disallows costs for which the hospital had requested an adjustment (see the definitions in § 405.1801(a) of this chapter and the provisions regarding a provider's right to a Board hearing in § 405.1835 of this chapter).

(5) *Extending time limit for PRRB review of NPR.* The time required to review the request is considered good cause for the granting of an extension of the time limit to apply for review of the notice of amount of program reimbursement by the Provider Reimbursement Review Board, as specified in § 405.1841(b) of this chapter.

(6) *Applicability.* The provisions in paragraphs (e)(1) through (e)(5) of this section apply to a hospital's initial request for an adjustment and to a request for a review of the original decision based on additional data.

(f) *Comparison to the target amount for new hospitals and units*—(1) *New hospitals and units*—(i) *New hospitals.* For purposes of this section, a new hospital is a provider of hospital inpatient services that—

(A) Has operated as the type of hospital for which CMS granted it approval to participate in the Medicare program, under present or previous ownership (or both), for less than 2 full years; and

(B) Has provided the type of hospital inpatient services for which CMS granted it approval to participate in the Medicare program, for less than 2 years.

(ii) *New units.* A newly established unit that is excluded from the prospective payments system under the provisions of §§ 412.25 through 412.30 of this chapter does not qualify for the exemption afforded to a new hospital under paragraph (f)(2)(i) of this section unless the unit is located in an acute care hospital that, if it were subject to the provisions of this section, would qualify as a new hospital under paragraph (f)(1)(i) of this section.

(2) *Comparison*—(i) *Exemptions.* (A) A new children's hospital is exempt from

the rate-of-increase ceiling imposed under this section. The exemption begins when the hospital accepts its first patient and ends at the end of the first cost reporting period ending at least 2 years after the hospital accepts its first patient. The first cost reporting period of at least 12 months beginning at least 1 year after the hospital accepts its first patient is the base year, in accordance with paragraph (b) of this section.

(B) Within 180 days of the date a hospital is excluded from the prospective payment system, the intermediary determines whether the hospital is exempt from the rate-of-increase ceiling. The intermediary notifies the hospital of its determination and the hospital's base period.

(C) A decision issued under paragraph (f)(2)(ii)(B) of this section is considered final unless the hospital submits additional information and requests a review of the decision no later than 180 days after the date on the intermediary's notice of the decision. The final decision is subject to review under subpart R of part 405 of this chapter, provided the hospital has received a notice of program reimbursement (NPR) for the cost reporting period in question and the NPR does not reflect an exemption (see the definitions in § 405.1801(a) of this chapter and the provisions regarding a provider's right to a Board hearing in § 405.1835 of this chapter).

(ii) *Median target amount.* (A) For cost reporting periods beginning on or after October 1, 1997, the amount of payment for a new psychiatric hospital or unit, a new rehabilitation hospital or unit, or a new long-term care hospital that was not paid as an excluded hospital prior to October 1, 1997, is the lower of the hospital's net inpatient operating cost per case or 110 percent of the national median of the target amounts for the class of excluded hospitals and units (psychiatric, rehabilitation, long-term care) as adjusted for differences in wage levels and updated to the first cost reporting period in which the hospital receives payment. The second cost reporting period is subject to the same target amount as the first cost reporting period.

(B) The national median of the target amounts is the FY 1996 median target amount—

(*1*) Adjusted to account for differences in area wage levels;

(*2*) Updated by the market basket percentage increase to the fiscal year in which the hospital first received payments as an excluded provider.

(3) *Risk-basis HMOs.* Items or services that are furnished to beneficiaries enrolled in an HMO by a hospital that is either owned or operated by a risk-basis HMO or related to a risk-basis HMO by common ownership or control are exempt from the rate-of-increase ceiling (see the definition of an entity with a risk sharing contract in § 417.401 of this chapter).

(g) *Adjustments*—(1) *General rules.* (i) CMS adjusts the amount of the operating costs considered in establishing the rate-of-increase ceiling for one or more cost reporting periods, including both periods subject to the ceiling and the hospital's base period, under the circumstances specified in paragraphs (g)(2), (g)(3), and (g)(4) of this section.

(ii) When the hospital requests an adjustment, CMS makes an adjustment only to the extent that the hospital's operating costs are reasonable, attributable to the circumstances specified separately, identified by the hospital, and verified by the intermediary.

(iii) When the hospital requests an adjustment, CMS makes an adjustment only if the hospital's operating costs exceed the rate-of-increase ceiling imposed under this section.

(iv) In the case of a psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital, the amount of payment under paragraph (g)(3) of this section may not exceed the payment amount based on the target amount determined under paragraph (c)(4)(iii) of this section.

(v) In the case of a hospital or unit that received a revised FY 1998 target amount under the rebasing provisions of paragraph (b)(1)(iv) of this section, the amount of an adjustment payment for a cost reporting period is based on a comparison of the hospital's operating costs for the cost reporting period to the average costs and statistics for the cost reporting periods used to

determine the FY 1998 rebased target amount.

(2) *Extraordinary circumstances.* CMS may make an adjustment to take into account unusual costs (in either a cost reporting period subject to the ceiling or the hospital's base period) due to extraordinary circumstances beyond the hospital's control. These circumstances include, but are not limited to, strikes, fire, earthquakes, floods, or similar unusual occurrences with substantial cost effects.

(3) *Comparability of cost reporting periods*—(i) *Adjustment for distortion.* CMS may make an adjustment to take into account factors that would result in a significant distortion in the operating costs of inpatient hospital services between the base year and the cost reporting period subject to the limits.

(ii) *Factors.* The adjustments described in paragraph (g)(3)(i) of this section, include, but are not limited to, adjustments to take into account:

(A) FICA taxes (if the hospital did not incur costs for FICA taxes in its base period).

(B) Services billed under part B of Medicare during the base period, but paid under part A during the subject cost reporting period.

(C) Malpractice insurance costs (if malpractice costs were not included in the base year operating costs).

(D) Increases in service intensity or length of stay attributable to changes in the type of patient served.

(E) A change in the inpatient hospital services that a hospital provides, and that are customarily provided directly by similar hospitals, such as an addition or discontinuation of services or treatment programs.

(F) The manipulation of discharges to increase reimbursement.

(iii) *Adjusting operating costs.* Without a formal request from a hospital, CMS may adjust the amount of operating costs determined under paragraph (c)(1) of this section to take into account certain adjustments. These adjustments include, but are not limited to, adjustments under paragraphs (g)(3)(ii)(A), (B), (C), (E), and (F) of this section.

(4) *Significant wage increase.* (i) *Criteria.* CMS may make an adjustment to take into account a significant increase in wages occurring between the base period and the cost reporting period subject to the ceiling if there is a significant increase in the average hourly wage for the geographic area in which the hospital is located (determined by reference to the wage index for prospective payment hospitals without regard to geographic reclassifications under sections 1886(d)(8) and (10) of the Act). For this purpose, there is a significant wage increase if the wage index value based on wage survey data collected for the cost reporting period subject to the ceiling is at least 8.0 percent higher than the wage index value based on survey data collected for the base year cost reporting period. If survey data are not available for the cost reporting periods used in the comparison, the wage index value based on the latest available survey data collected prior to that cost reporting period is used.

(ii) *Amount of the adjustment.* The adjustment for a significant wage increase equals the amount by which the lesser of the following calculations exceeds 108 percent of the increase in the national average hourly earnings for hospital workers:

(A) The rate of increase in the average hourly wage in the geographic area (determined by applying the applicable increase in the area wage index value to the rate of increase in the national average hourly earnings for hospital workers).

(B) The rate of increase in the hospital's average hourly wage.

(5) *Adjustment limitations.* For cost reporting periods beginning on or after October 1, 1993, and before October 1, 2003, the payment reductions under paragraph (c)(3)(v) through (c)(3)(vii) of this section will not be considered when determining adjustments under this paragraph.

(h) [Reserved]

(i) *Assignment of a new base period.* (1) *General rule.* (i) Effective with cost reporting periods beginning on or after April 1, 1990, CMS may assign a new base period to establish a revised ceiling if the new base period is more representative of the reasonable and necessary cost of furnishing inpatient services and all the following conditions apply:

(A) The actual allowable inpatient costs of the hospital in the cost reporting period that would be affected by the revised ceiling exceed the target amount established under paragraph (c) of this section.

(B) The hospital documents that the higher costs are the result of substantial and permanent changes in furnishing patient care services since the base period. In making this determination, CMS takes into consideration the following factors:

(*1*) Changes in the services provided by the hospital.

(*2*) Changes in applicable technologies and medical practices.

(*3*) Differences in the severity of illness among patients or types of patients served.

(C) The adjustments described in paragraph (g) of this section would not result in recognition of the reasonable and necessary costs of providing inpatient services.

(ii) The revised ceiling is based on the necessary and proper costs incurred during the new base period.

(A) Increases in overhead costs (for example, administrative and general costs and housekeeping costs) are not taken into consideration unless the hospital documents that these increases result from substantial and permanent changes in furnishing patient care services.

(B) In determining whether wage increases are necessary and proper, CMS takes into consideration whether increases in wages and wage-related costs for hospitals in the labor market area exceed the national average increase.

(2) *New base period.* The new base period is the first cost reporting period that is 12 months or longer that reflects the substantial and permanent change.

(3) *New applicable rate-of-increase percentages and update factors.* The revised target amount resulting from the assignment of a new base period is increased by the applicable rate-of-increase percentages (update factors) described in paragraph (c)(3) of this section.

(j) *Reduction to capital-related costs.* For psychiatric hospital and units, rehabilitation hospitals and units, and long-term care hospitals, the amount otherwise payable for capital-related costs for hospital inpatient services is reduced by 15 percent for portions of cost reporting periods occurring on or after October 1, 1997 through September 30, 2002.

[58 FR 46340, Sept. 1, 1993, as amended at 59 FR 1659, Jan. 12, 1994; 59 FR 45401, Sept. 1, 1994; 60 FR 45849, Sept. 1, 1995; 61 FR 2725, Jan. 29, 1996; 61 FR 46225, Aug. 30, 1996; 62 FR 46032, Aug. 29, 1997; 63 FR 6868, Feb. 11, 1998; 63 FR 26358, May 12, 1998; 63 FR 41004, July 31, 1998; 64 FR 41541, July 30, 1999; 65 FR 47049, 47108, Aug. 1, 2000; 66 FR 32194, June 13, 2001; 66 FR 41394, Aug. 7, 2001; 67 FR 50114, Aug. 1, 2002; 69 FR 49252, Aug. 11, 2004; 69 FR 66981, Nov. 15, 2004; 70 FR 47487, Aug. 12, 2005]

Subpart D—Apportionment

§ 413.50 Apportionment of allowable costs.

(a) Consistent with prevailing practice in which third-party organizations pay for health care on a cost basis, reimbursement under the Medicare program involves a determination of—

(1) Each provider's allowable costs for producing services; and

(2) The share of these costs which is to be borne by Medicare. The provider's costs are to be determined in accordance with the principles reviewed in the preceding discussion relating to allowable costs. The share to be borne by Medicare is to be determined in accordance with principles relating to apportionment of cost.

(b) In the study and consideration devoted to the method of apportioning costs, the objective has been to adopt methods for use under Medicare that would, to the extent reasonably possible, result in the program's share of a provider's total allowable costs being the same as the program's share of the provider's total services. This result is essential for carrying out the statutory directive that the program's payments to providers should be such that the costs of covered services for beneficiaries would not be passed on to nonbeneficiaries, nor would the cost of services for nonbeneficiaries be borne by the program.

(c) A basic factor bearing upon apportionment of costs is that Medicare beneficiaries are not a cross section of the total population. Nor will they constitute a cross section of all patients

receiving services from most of the providers that participate in the program. Available evidence shows that the use of services by persons age 65 and over differs significantly from other groups. Consequently, the objective sought in the determination of the Medicare share of a provider's total costs means that the methods used for apportionment must take into account the differences in the amount of services received by patients who are beneficiaries and other patients serviced by the provider.

(d) The method of cost reimbursement most widely used at the present time by third-party purchasers of inpatient hospital care apportions a provider's total costs among groups served on the basis of the relative number of days of care used. This method, commonly referred to as average-per-diem cost, does not take into account, variations in the amount of service which a day of care may represent and thereby assumes that the patients for whom payment is made on this basis are average in their use of service.

(e) In considering the average-per-diem method of apportioning cost for use under the program, the difficulty encountered is that the preponderance of presently available evidence strongly indicates that the over-age 65 patient is not typical from the standpoint of average-per-diem cost. On the average this patient stays in the hospital twice as long and therefore the ancillary services that he uses are averaged over the longer period of time, resulting in an average-per-diem cost for the aged alone, significantly below the average-per-diem for all patients.

(f) Moreover, the relative use of services by aged patients as compared to other patients differs significantly among institutions. Consequently, considerations of equity among institutions are involved as well as that of effectiveness of the apportionment method under the program in accomplishing the objective of paying each provider fully, but only for services to beneficiaries.

(g) A further consideration of long-range importance is that the relative use of services by aged and other patients can be expected to change, possibly to a significant extent in future years. The ability of apportionment methods used under the program to reflect such change is an element of flexibility which has been regarded as important in the formulation of the cost reimbursement principles.

(h) An alternative to the relative number of days of care as a basis for apportioning costs is the relative amount of charges billed by the provider for services to patients. The amount of charges is the basis upon which the cost of hospital care is distributed among patients who pay directly for the services they receive. Payment for services on the basis of charges applies generally under insurance programs in which individuals are indemnified for incurred expenses, a form of health insurance widely held throughout the United States. Also, charges to patients are commonly a factor in determining the amount of payment to hospitals under insurance programs providing service benefits, many of which pay ''costs or charges, whichever is less'' and some of which pay exclusively on the basis of charges. In all of these instances, the provider's own charge structure and method of itemizing services for the purpose of assessing charges is utilized as a measure of the amount of services received and as the basis for allocating responsibility for payment among those receiving the provider's services.

(i) An increasing number of third-party purchasers who pay for services on the basis of cost are developing methods that utilize charges to measure the amount of services for which they have responsibility for payment. In this approach, the amount of charges for such services as a proportion of the provider's total charges to all patients is used to determine the proportion of the provider's total costs for which the third-party purchaser assumes responsibility. The approach is subject to numerous variations. It can be applied to the total of charges for all services combined or it can be applied to components of the provider's activities for which the amount of costs and charges are ascertained through a breakdown of data from the provider's accounting records.

(j) For the application of the approach to components, which represent

types of services, the breakdown of total costs is accomplished by ''cost-finding'' techniques under which indirect costs and nonrevenue activities are allocated to revenue producing components for which charges are made as services are furnished.

§ 413.53 Determination of cost of services to beneficiaries.

(a) *Principle.* Total allowable costs of a provider will be apportioned between program beneficiaries and other patients so that the share borne by the program is based upon actual services received by program beneficiaries. The methods of apportionment are defined as follows:

(1) *Departmental method*—(i) *Methodology.* Except as provided in paragraph (a)(1)(ii) of this section with respect to the treatment of the private room cost differential for cost reporting periods starting on or after October 1, 1982, the ratio of beneficiary charges to total patient charges for the services of each ancillary department is applied to the cost of the department; to this is added the cost of routine services for program beneficiaries, determined on the basis of a separate average cost per diem for general routine patient care areas as defined in paragraph (b) of this section, taking into account, in hospitals, a separate average cost per diem for each intensive care unit, coronary care unit, and other intensive care type inpatient hospital units.

(ii) *Exception: Indirect cost of private rooms.* For cost reporting periods starting on or after October 1, 1982, except with respect to a hospital receiving payment under part 412 of this chapter (relating to the prospective payment system), the additional cost of furnishing services in private room accommodations is apportioned to Medicare only if these accommodations are furnished to program beneficiaries, and are medically necessary. To determine routine service cost applicable to beneficiaries—

(A) Multiply the average cost per diem (as defined in paragraph (b) of this section) by the total number of Medicare patient days (including private room days whether or not medically necessary);

(B) Add the product of the average per diem private room cost differential (as defined in paragraph (b) of this section) and the number of medically necessary private room days used by beneficiaries; and

(C) Effective October 1, 1990, do not include private rooms furnished for SNF-type and NF-type services under the swing-bed provision in the number of days in paragraphs (a)(1)(ii)(A) and (B) of this section.

(2) *Carve-out out method*—(i) The carve-out out method is used to allocate hospital inpatient general routine service costs in a participating swing-bed hospital, as defined in § 413.114(b). Under this method, effective for services furnished on or after October 1, 1990, the reasonable costs attributable to the inpatient routine SNF-type and NF-type services furnished to all classes of patients are subtracted from total inpatient routine service costs before computing the average cost per diem for inpatient routine hospital care.

(ii) The cost per diem attributable to the routine SNF-type services covered by Medicare is based on the regional Medicare swing-bed SNF rate in effect for a given calendar year, as described in § 413.114(c). The Medicare SNF rate applies only to days covered and paid as Medicare days. When Medicare coverage runs out, the Medicare rate no longer applies.

(iii) The cost per diem attributable to all non-Medicare swing-bed days is based on the average statewide Medicaid NF rate for the prior calendar year, adjusted to approximate the average NF rate for the current calendar year.

(iv) The sum of total Medicare SNF-type days multiplied by the cost per diem attributable to Medicare SNF-type services and the total NF-type days multiplied by the cost per diem attributable to all non-Medicare days is subtracted from total inpatient general routine service costs. The cost per diem for inpatient routine hospital care is computed based on the remaining inpatient routine service costs.

(3) *Cost per visit by type-of-service method—HHAs.* For cost reporting periods beginning on or after October 1, 1980, all HHAs must use the cost per

visit by type-of-service method of apportioning costs between Medicare and non-Medicare beneficiaries. Under this method, the total allowable cost of all visits for each type of service is divided by the total number of visits for that type of service. Next, for each type of service, the number of Medicare covered visits is multiplied by the average cost per visit just computed. This represents the cost Medicare will recognize as the cost for that service, subject to cost limits published by CMS (see § 413.30).

(b) *Definitions*. As used in this section—

Ancillary services means the services for which charges are customarily made in addition to routine services.

Apportionment means an allocation or distribution of allowable cost between the beneficiaries of the Medicare program and other patients.

Average cost per diem for general routine services means the following:

(1) For cost reporting periods beginning on or after October 1, 1982, subject to the provisions on swing-bed hospitals, the average cost of general routine services net of the private room cost differential. The average cost per diem is computed by the following methodology:

(i) Determine the total private room cost differential by multiplying the average per diem private room cost differential determined in paragraph (c) of this section by the total number of private room patient days.

(ii) Determine the total inpatient general routine service costs net of the total private room cost differential by subtracting the total private room cost differential from total inpatient general routine service costs.

(iii) Determine the average cost per diem by dividing the total inpatient general routine service cost net of private room cost differential by all inpatient general routine days, including total private room days.

(2) For swing-bed hospitals, the amount computed by—(i) Subtracting the routine costs associated with Medicare SNF-type days and non-Medicare NF-type days from the total allowable inpatient cost for routine services (excluding the cost of services provided in intensive care units, coronary care units, and other intensive care type inpatient hospital units and nursery costs); and

(ii) Dividing the remainder (excluding the total private room cost differential) by the total number of inpatient hospital days of care (excluding Medicare SNF-type days and non-Medicare NF-type days of care, days of care in intensive care units, coronary care units, and other intensive care type inpatient hospital units; and newborn days; but including total private room days).

Average cost per diem for hospital intensive care type units means the amount computed by dividing the total allowable costs for routine services in each of these units by the total number of inpatient days of care furnished in each of these units.

Average per diem private room cost differential means the difference in the average per diem cost of furnishing routine services in a private room and in a semi-private room. (This differential is not applicable to hospital intensive care type units.) (The method for computing this differential is described in paragraph (c) of this section.)

Charges means the regular rates for various services that are charged to both beneficiaries and other paying patients who receive the services. Implicit in the use of charges as the basis for apportionment is the objective that charges for services be related to the cost of the services.

Intensive care type inpatient hospital unit means a hospital unit that furnishes services to critically ill inpatients. Examples of intensive care type units include, but are not limited to, intensive care units, trauma units, coronary care units, pulmonary care units, and burn units. Excluded as intensive care type units are postoperative recovery rooms, postanesthesia recovery rooms, maternity labor rooms, and subintensive or intermediate care units. (The unit must also meet the criteria of paragraph (d) of this section.)

Nursing facility (NF)-type services, formerly known as ICF and SNF-type services, are routine services furnished by a swing-bed hospital to Medicaid and other non-Medicare patients. Under the Medicaid program, effective

October 1, 1990, facilities are no longer certified as SNFs or ICFs but instead are certified only as NFs and can provide services as defined in section 1919(a)(1) of the Act.

Skilled nursing facility (SNF)-type services are routine services furnished by a swing-bed hospital that would constitute extended care services if furnished by an SNF. SNF-type services include routine SNF services furnished in the distinct part SNF of a hospital complex that is combined with the hospital general routine service area cost center under § 413.24(d)(5). Effective October 1, 1990, only Medicare covered services are included in the definition of SNF-type services.

Ratio of beneficiary charges to total charges on a departmental basis means the ratio of charges to beneficiaries of the Medicare program for services of a revenue-producing department or center to the charges to all patients for that center during an accounting period. After each revenue-producing center's ratio is determined, the cost of services furnished to beneficiaries of the Medicare program is computed by applying the individual ratio for the center to the cost of the related center for the period.

Routine services means the regular room, dietary, and nursing services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made.

(c) *Method for computing the average per diem private room cost differential.* Compute the average per diem private room cost differential as follows:

(1) Determine the average per diem private room charge differential by subtracting the average per diem charge for all semi-private room accommodations from the average per diem charge for all private room accommodations. The average per diem charge for private room accommodations is determined by dividing the total charges for private room accommodations by the total number of days of care furnished in private room accommodations. The average per diem charge for semi-private accommodations is determined by dividing the total charges for semi-private room accommodations by the total number of days of care furnished in semi-private accommodations.

(2) Determine the inpatient general routine cost to charge ratio by dividing total inpatient general routine service cost by the total inpatient general routine service charges.

(3) Determine the average per diem private room cost differential by multiplying the average per diem private room charge differential determined in paragraph (c)(1) of this section by the ratio determined in paragraph (c)(2) of this section.

(d) *Criteria for identifying intensive care type units.* For purposes of determining costs under this section, a unit will be identified as an intensive care type inpatient hospital unit only if the unit—

(1) Is in a hospital;

(2) Is physically and identifiably separate from general routine patient care areas, including subintensive or intermediate care units, and ancillary service areas. There cannot be a concurrent sharing f nursing staff between an intensive care type unit and units or areas furnishing different levels or types of care. However, two or more intensive care type units that concurrently share nursing staff can be reimbursed as one combined intensive care type unit if all other criteria are met. Float nurses (nurses who work in different units on an as-needed basis) can be utilized in the intensive care type unit. If a float nurse works in two different units during the same eight hour shift, then the costs must be allocated to the appropriate units depending upon the time spent in those units. The hospital must maintain adequate records to support the allocation. If such records are not available, then the costs must be allocated to the general routine services cost areas;

(3) Has specific written policies that include criteria for admission to, and discharge from, the unit;

(4) Has registered nursing care available on a continuous 24-hour basis with at least one registered nurse present in the unit at all times;

(5) Maintains a minimum nurse-patient ratio of one nurse to two patients per patient day. Included in the calculation of this nurse-patient ratio are registered nurses, licensed vocational

nurses, licensed practical nurses, and nursing assistants who provide patient care. Not included are general support personnel such as ward clerks, custodians, and housekeeping personnel; and

(6) Is equipped, or has available for immediate use, life-saving equipment necessary to treat the critically ill patients for which it is designed. This equipment may include, but is not limited to, respiratory and cardiac monitoring equipment, respirators, cardiac defibrillators, and wall or canister oxygen and compressed air.

(e) *Application*—(1) *Departmental method; Cost reporting periods beginning on or after October 1, 1982.*

(i) The following example illustrates how costs would be determined, using only inpatient data, for cost reporting periods beginning on or after October 1, 1982, based on apportionment of—

(A) The average cost per diem for general routine services (subject to the private room differential provisions of paragraph (a)(1)(iii) of this section);

(B) The average cost per diem for each intensive care type unit;

(C) The ratio of beneficiary charges to total charges applied to cost by department.

HOSPITAL Y

Department	Charges to program beneficiaries	Total charges	Ratio of beneficiary charges to total charges	Total cost	Cost of beneficiary services
	Percent				
Operating rooms	$20,000	$70,000	28 4/7	$77,000	$22,000
Delivery rooms	0	12,000	0	30,000	0
Pharmacy	20,000	60,000	33 1/3	45,000	15,000
X-ray	24,000	100,000	24	75,000	18,000
Laboratory	40,000	140,000	28 4/7	98,000	28,000
Others	6,000	30,000	20	25,000	5,000
Total	110,000	412,000	.....	350,000	88,000

	Total inpatient days	Total cost	Average cost per diem	Program in patient days	Cost of beneficiary services
General routine	30,000	$630,000	$21	8,000	$168,000
Coronary care unit	500	20,000	40	200	8,000
Intensive care unit	3,000	108,000	36	1,000	36,000
	33,500	758,000	.....	9,200	212,000
Total	.....	.....	.....	.....	300,000

(ii) The following illustrates how apportionment based on an average cost per diem for general routine services is determined.

HOSPITAL E

Facts	Private accommodations	Semi-private accommodations	Total
Total charges	$20,000	$175,000	$195,000
Total days	100	1,000	1,100
Programs days	70	400	470
Medically necessary for program beneficiaries	20	.....	20
Total general routine service costs	.....	.....	165,000
Average private room per diem charge ($20,000 private room charges ÷ 100 days)			[1] $200
Average semi-private room per diem charge ($175,000 semi-private charge ÷ 1,000 days)			[1] $175

[1] Per diem.

Average per diem private room cost differential.

1. Average per diem private room charge differential ($200 private room per diem—$175, semi-private room per diem), $25.
2. Inpatient general routine cost/charge ratio ($165,000 total costs ÷ $195,000 total charges), 0.8461538.
3. Average per diem private room cost differential ($25 charge differential × .8461538 cost/charge ratio), $21.15.

Average cost per diem for inpatient general routine services.

4. Total private room cost differential ($21.15 average per diem cost differential × 100 private room days), $2,115.

5. Total inpatient general routine service costs net of private room cost differential ($165,000 total routine cost − $2,115 private room cost differential), $162,885.

6. Average cost per diem for inpatient general routine services ($162,885 routine cost net of private room cost differential ÷ 1,100 patient days), $148.08.

Medicare general routine service cost.

7. Total routine per diem cost applicable to Medicare ($148.08 average cost per diem × 470 Medicare private and semi-private patient days), $69,598.

8. Total private room cost differential applicable to Medicare ($21.15 average per diem private room cost differential × 20 medically necessary private room days), $423.

9. Medicare inpatient general routine service cost ($423 Medicare private room cost differential + $69,598 Medicare cost of general routine inpatient services), $70,021.

(2) *Carve out method.* The following illustrates how apportionment is determined in a hospital reimbursed under the carve out method (subject to the private room differential provisions of paragraph (a)(1)(ii) of this section):

HOSPITAL K

[Determination of cost of routine SNF-type and ICF-type services and general routine hospital services[1]]

Facts	Days of care		
	General routine hospital	SNF-type	ICF-type
Total days of care	2,000	400	100
Medicare days of care ...	600	300	
Average Medicaid rate ..	N/A	$35	$20
Total inpatient general routine service costs: $250,000			

Calculation of cost of routine SNF-type services applicable to Medicare:

$35 × 300 = $10,500

Calculation of cost of general routine hospital services:

Cost of SNF-type services: $35 × 400	$14,000
Cost of ICF-type services: $20 × 100	2,000
Total	$16,000

Average cost per diem of general routine hospital services:

$250,000 − $16,000 ÷ 2,000 days = $117

Medicare general routine hospital cost:

$117 × 600 = $70,200

Total Medicare reasonable cost for general routine inpatient days:

$10,500 + $70,200 = $80,700

[51 FR 34793, Sept. 30, 1986, as amended at 59 FR 45401, Sept. 1, 1994; 61 FR 51616, Oct. 3, 1996; 61 FR 58631, Nov. 18, 1996]

§ 413.56 [Reserved]

Subpart E—Payments to Providers

§ 413.60 Payments to providers: General.

(a) The fiscal intermediaries will establish a basis for interim payments to each provider. This may be done by one of several methods. If an intermediary is already paying the provider on a cost basis, the intermediary may adjust its rate of payment to an estimate of the result under the Medicare principles of reimbursement. If no organization is paying the provider on a cost basis, the intermediary may obtain the previous year's financial statement from the provider and, by applying the principles of reimbursement, compute or approximate an appropriate rate of payment. The interim payment may be related to the last year's average per diem, or to charges, or to any other ready basis of approximating costs.

(b) At the end of the period, the actual apportionment, based on the cost finding and apportionment methods selected by the provider, determines the Medicare reimbursement for the actual services provided to beneficiaries during the period.

(c) Basically, therefore, interim payments to providers will be made for services throughout the year, with final settlement on a retroactive basis at the end of the accounting period. Interim payments will be made as often as possible and in no event less frequently than once a month. The retroactive payments will take fully into account the costs that were actually incurred and settle on an actual, rather than on an estimated basis.

§ 413.64 Payments to providers: Specific rules.

(a) *Reimbursement on a reasonable cost basis.* Providers of services paid on the basis of the reasonable cost of services furnished to beneficiaries will receive interim payments approximating the actual costs of the provider. These payments will be made on the most expeditious schedule administratively feasible but not less often than monthly. A retroactive adjustment based on actual costs will be made at the end of a reporting period.

(b) *Amount and frequency of payment.* Medicare states that providers of services will be paid the reasonable cost of services furnished to beneficiaries. Since actual costs of services cannot be determined until the end of the accounting period, the providers must be paid on an estimated cost basis during the year. While Medicare provides that interim payments will be made no less often than monthly, intermediaries are expected to make payments on the most expeditious basis administratively feasible. Whatever estimated cost basis is used for determining interim payments during the year, the intent is that the interim payments shall approximate actual costs as nearly as is practicable so that the retroactive adjustment based on actual costs will be as small as possible.

(c) *Interim payments during initial reporting period.* At the beginning of the program or when a provider first participates in the program, it will be necessary to establish interim rates of payment to providers of services. Once a provider has filed a cost report under the Medicare program, the cost report may be used as a basis for determining the interim rate of reimbursement for the following period. However, since initially there is no previous history of cost under the program, the interim rate of payment must be determined by other methods, including the following:

(1) If the intermediary is already paying the provider on a cost or cost-related basis, the intermediary will adjust its rate of payment to the program's principles of reimbursement. This rate may be either an amount per inpatient day, or a percent of the provider's charges for services furnished to the program's beneficiaries.

(2) If an organization other than the intermediary is paying the provider for services on a cost or cost-related basis, the intermediary may obtain from that organization or from the provider itself the rate of payment being used and other cost information as may be needed to adjust that rate of payment to give recognition to the program's principles of reimbursement.

(3) It no organization is paying the provider on a cost or cost-related basis, the intermediary will obtain the previous year's financial statement from the provider. By analysis of such statement in light of the principles of reimbursement, the intermediary will compute an appropriate rate of payment.

(4) After the initial interim rate has been set, the provider may at any time request, and be allowed, an appropriate increase in the computed rate, upon presentation of satisfactory evidence to the intermediary that costs have increased. Likewise, the intermediary may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

(d) *Interim payments for new providers.* (1) Newly-established providers will not have cost experience on which to base a determination of an interim rate of payment. In such cases, the intermediary will use the following methods to determine an appropriate rate:

(i) If there is a provider or providers comparable in substantially all relevant factors to the provider for which the rate is needed, the intermediary will base an interim rate of payment on the costs of the comparable provider.

(ii) If there are no substantially comparable providers from whom data are available, the intermediary will determine an interim rate of payment based on the budgeted or projected costs of the provider.

(2) Under either method, the intermediary will review the provider's cost experience after a period of three months. If need for an adjustment is indicated, the interim rate of payment will be adjusted in line with the provider's cost experience.

(e) *Interim payments after initial reporting period.* Interim rates of payment for services provided after the initial reporting period will be established on the basis of the cost report filed for the previous year covering Medicare services. The current rate will be determined—whether on a per diem or percentage of charges basis—using the previous year's costs of covered services and making any appropriate adjustments required to bring, as closely as possible, the current year's rate of interim payment into agreement with current year's costs. This interim rate of payment may be adjusted by the intermediary during an

accounting period if the provider submits appropriate evidence that its actual costs are or will be significantly higher than the computed rate. Likewise, the intermediary may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

(f) *Retroactive adjustment.* (1) Medicare provides that providers of services will be paid amounts determined to be due, but not less often than monthly, with necessary adjustments due to previously made overpayments or underpayments. Interim payments are made on the basis of estimated costs. Actual costs reimbursable to a provider cannot be determined until the cost reports are filed and costs are verified. Therefore, a retroactive adjustment will be made at the end of the reporting period to bring the interim payments made to the provider during the period into agreement with the reimbursable amount payable to the provider for the services furnished to program beneficiaries during that period.

(2) In order to reimburse the provider as quickly as possible, an initial retroactive adjustment will be made as soon as the cost report is received. For this purpose, the costs will be accepted as reported, unless there are obvious errors or inconsistencies, subject to later audit. When an audit is made and the final liability of the program is determined, a final adjustment will be made.

(3) To determine the retroactive adjustment, the amount of the provider's total allowable cost apportioned to the program for the reporting year is computed. This is the total amount of reimbursement the provider is due to receive from the program and the beneficiaries for covered services furnished during the reporting period. The total of the interim payments made by the program in the reporting year and the deductibles and coinsurance amounts receivable from beneficiaries is computed. The difference between the reimbursement due and the payments made is the amount of the retroactive adjustment.

(g) *Accelerated payments to providers.* Upon request, an accelerated payment may be made to a provider of services that is not receiving periodic interim payments under paragraph (h) of this section if the provider has experienced financial difficulties due to a delay by the intermediary in making payments or in exceptional situations, in which the provider has experienced a temporary delay in preparing and submitting bills to the intermediary beyond its normal billing cycle. Any such payment must be approved first by the intermediary and then by CMS. The amount of the payment is computed as a percentage of the net reimbursement for unbilled or unpaid covered services. Recovery of the accelerated payment may be made by recoupment as provider bills are processed or by direct payment.

(h) *Periodic interim payment method of reimbursement*—(1) *Covered services furnished before July 1, 1987.* In addition to the regular methods of interim payment on individual provider billings for covered services, the periodic interim payment (PIP) method is available for Part A hospital and SNF inpatient services.

(2) *Covered services furnished on or after July 1, 1987.* Effective with claims received on or after July 1, 1987, or as otherwise specified, the periodic interim payment (PIP) method is available for the following:

(i) Part A inpatient services furnished in hospitals that are excluded from the prospective payment systems, as specified in § 412.1(a)(1) of this chapter under subpart B of part 412 of this subchapter, or are paid under the prospective payment systems described in subpart N, O, and P of part 412 of this chapter.

(ii) Part A services furnished in hospitals receiving payment in accordance with a demonstration project authorized under section 402(a) of Public Law 90–248 (42 U.S.C. 1395b–1) or section 222(a) of Public Law 92–603 (42 U.S.C. 1395b–1 (note)), or a State reimbursement control system approved under section 1886(c) of the Act and subpart C of part 403 of this chapter, if that type of payment is specifically approved by CMS as an integral part of the demonstration or control system. If that type of payment is not an integral part of the demonstration or control system, PIP is available for the hospital under paragraph (h)(1)(i) of this section

for hospitals excluded from the prospective payment systems or under § 412.116(b) of this chapter for prospective payment hospitals.

(iii) Part A SNF services furnished in cost reporting periods beginning before July 1, 1998. (For services furnished in subsequent cost reporting periods, see § 413.350 regarding periodic interim payments for skilled nursing facilities).

(iv) Part A services furnished in hospitals paid under the prospective payment system, including distinct part psychiatric or rehabilitation units, as described in § 412.116(b) of this chapter.

(v) Services furnished in a hospice as specified in part 418 of this chapter. Payment on a PIP basis is described in § 418.307 of this chapter.

(vi) Effective for payments made on or after July 1, 2004, inpatient CAH services furnished by a CAH as specified in § 413.70. Payment on a PIP basis is described in § 413.70(d).

(3) Any participating provider furnishing the services described in paragraphs (h)(1) and (h)(2) of this section that establishes to the satisfaction of the intermediary that it meets the following requirements may elect to be reimbursed under the PIP method, beginning with the first month after its request that the intermediary finds administratively feasible:

(i) The provider's estimated total Medicare reimbursement for inpatient services is at least $25,000 a year computed under the PIP formula or, in the case of an HHA, either its estimated—

(A) Total Medicare reimbursement for Part A and Part B services is at least $25,000 a year computed under the PIP formula; or

(B) Medicare reimbursement computed under the PIP formula is at least 50 percent of estimated total allowable cost.

(ii) The provider has filed at least one completed Medicare cost report accepted by the intermediary as providing an accurate basis for computation of program payment (except in the case of a provider requesting reimbursement under the PIP method upon first entering the Medicare program).

(iii) The provider has the continuing capability of maintaining in its records the cost, charge, and statistical data needed to accurately complete a Medicare cost report on a timely basis.

(4) [Reserved]

(5) The intermediary's approval of a provider's request for reimbursement under the PIP method will be conditioned upon the intermediary's best judgment as to whether payment can be made to the provider under the PIP method without undue risk of its resulting in an overpayment because of greatly varying or substantially declining Medicare utilization, inadequate billing practices, or other circumstances. The intermediary may terminate PIP reimbursement to a provider at any time it determines that the provider no longer meets the qualifying requirements or that the provider's experience under the PIP method shows that proper payment cannot be made under this method.

(6) Payment will be made biweekly under the PIP method unless the provider requests a longer fixed interval (not to exceed one month) between payments. The payment amount will be computed by the intermediary to approximate, on the average, the cost of covered inpatient or home health services furnished by the provider during the period for which the payment is to be made, and each payment will be made two weeks after the end of such period of services. Upon request, the intermediary will, if feasible, compute the provider's payments to recognize significant seasonal variation in Medicare utilization of services on a quarterly basis starting with the beginning of the provider's reporting year.

(7) A provider's PIP amount may be appropriately adjusted at any time if the provider presents or the intermediary otherwise obtains evidence relating to the provider's costs or Medicare utilization that warrants such adjustment. In addition, the intermediary will recompute the payment immediately upon completion of the desk review of a provider's cost report and also at regular intervals not less often than quarterly. The intermediary may make a retroactive lump sum interim payment to a provider, based upon an increase in its PIP amount, in order to bring past interim payments for the provider's current cost reporting period into line with the adjusted

payment amount. The objective of intermediary monitoring of provider costs and utilization is to assure payments approximating, as closely as possible, the reimbursement to be determined at settlement for the cost reporting period. A significant factor in evaluating the amount of the payment in terms of the realization of the projected Medicare utilization of services is the timely submittal to the intermediary of completed admission and billing forms. All providers must complete billings in detail under this method as under regular interim payment procedures.

(i) *Bankruptcy or insolvency of provider*. If on the basis of reliable evidence, the intermediary has a valid basis for believing that, with respect to a provider, proceedings have been or will shortly be instituted in a State or Federal court for purposes of determining whether such provider is insolvent or bankrupt under an appropriate State or Federal law, any payments to the provider will be adjusted by the intermediary, notwithstanding any other regulation or program instruction regarding the timing or manner of such adjustments, to a level necessary to insure that no overpayment to the provider is made.

(j) *Interest payments resulting from judicial review*—(1) *Application*. If a provider of services seeks judicial review by a Federal court (see § 405.1877 of this chapter) of a decision furnished by the Provider Reimbursement Review Board or subsequent reversal, affirmation, or modification by the Secretary, the amount of any award of such Federal court will be increased by interest payable by the party against whom the judgment is made (see § 413.153 for treatment of interest). The interest is payable for the period beginning on the first day of the first month following the 180-day period which began on either the date the intermediary made a final determination or the date the intermediary would have made a final determination had it been done on a timely basis (see §§ 405.1835(b) and 405.1841(a) of this chapter).

(2) *Amount due*. Section 1878(f) of the Act, 42 U.S.C. 1395oo(f), authorizes a court to award interest in favor of the prevailing party on any amount due as a result of the court's decision. If the intermediary withheld any portion of the amount in controversy prior to the date the provider seeks judicial review by a Federal court, and the Medicare program is the prevailing party, interest is payable by the provider only on the amount not withheld. Similarly, if the Medicare program seeks to recover amounts previously paid to a provider, and the provider is the prevailing party, interest on the amounts previously paid to a provider is not payable by the Medicare program since that amount had been paid and is not due the provider.

(3) *Rate*. The amount of interest to be paid is equal to the rate of return on equity capital (see § 413.157) in effect for the month in which the civil action is commenced.

Example: An intermediary made a final determinaton on the amount of Medicare program reimbursement on June 15, 1974, and the provider appealed that determination to the Provider Reimbursement Review Board. The Board heard the appeal and rendered a decision adverse to the provider. On October 28, 1974, the provider commenced civil action to have such decision reviewed. The rate of return on equity capital for the month of October 1974 was 11.625 percent. The period for which interest is computed begins on January 1, 1975, and the interest beginning January 1, 1975, would be at the rate of 11.625 percent per annum.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 42238, Nov. 24, 1986; 53 FR 1628, Jan. 21, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 36713, July 19, 1994; 64 FR 41682, July 30, 1999; 65 FR 41211, July 3, 2000; 66 FR 41394, Aug. 7, 2001; 67 FR 56056, Aug. 30, 2002; 69 FR 49252, Aug. 11, 2004; 69 FR 66981, Nov. 15, 2004]

§ 413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) *Scope and definitions*. (1) *Scope*. (i) This section applies to all facilities for which provider-based status is sought, including remote locations of hospitals, as defined in paragraph (a)(2) of this section and satellite facilities as defined in § 412.22(h)(1) and § 412.25(e)(1) of this chapter, other than facilities described in paragraph (a)(1)(ii) of this section.

(ii) The determinations of provider-based status for payment purposes described in this section are not made as

to whether the following facilities are provider-based:

(A) Ambulatory surgical centers (ASCs).

(B) Comprehensive outpatient rehabilitation facilities (CORFs).

(C) Home health agencies (HHAs).

(D) Skilled nursing facilities (SNFs) (determinations for SNFs are made in accordance with the criteria set forth in § 483.5 of this chapter).

(E) Hospices.

(F) Inpatient rehabilitation units that are excluded from the inpatient PPS for acute hospital services.

(G) Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services (as defined in section 1861(jj) of the Act), facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services.

(H) Facilities, other than those operating as parts of CAHs, furnishing only physical, occupational, or speech therapy to ambulatory patients, for as long as the $1,500 annual cap on coverage of physical, occupational, or speech therapy, as described in section 1833(g)(2) of the Act, remains suspended by the action of subsequent legislation.

(I) ESRD facilities (determinations for ESRD facilities are made under § 413.174 of this chapter).

(J) Departments of providers that perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments).

(K) Ambulances.

(L) Rural health clinics (RHCs) affiliated with hospitals having 50 or more beds.

(2) *Definitions*. In this subpart E, unless the context indicates otherwise—

Campus means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term ''department of a provider'' does not include an RHC or, except as specified in paragraph (n) of this section, an FQHC.

Free-standing facility means an entity that furnishes health care services to Medicare beneficiaries and that is not integrated with any other entity as a main provider, a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity.

Main provider means a provider that either creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.

Provider-based entity means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the

Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

Provider-based status means the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.

Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term ''remote location of a hospital'' does not include a satellite facility as defined in § 412.22(h)(1) and § 412.25(e)(1) of this chapter.

(b) *Provider-based determinations.*—(1) A facility or organization is not entitled to be treated as provider-based simply because it or the main provider believe it is provider-based.

(2) If a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. The requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (h), and (i) of this section will not apply to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. For purposes of this paragraph (b)(2), a facility is considered as provider-based on October 1, 2000 if, on that date, it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital.

(3)(i) Except as specified in paragraphs (b)(2) and (b)(5) of this section, if a potential main provider seeks a determination of provider-based status for a facility that is located on the campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and, if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider seeking such a determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS and to CMS contractors upon request. If the facility is operated as a joint venture, the provider would also have to attest that it will comply with the requirements of paragraph (f) of this section.

(ii) If the facility is not located on the campus of the potential main provider, the provider seeking a determination would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated under a management contract, the requirements of paragraph (h) of this section. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations.

(iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as described in paragraph (b)(3)(i) of

this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(iv) Whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, as described in paragraph (b)(3)(ii) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, consistency with the documentation submitted with the attestation and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(4) A facility that is not located on the campus of a hospital and that is used as a site where physician services of the kind ordinarily furnished in physician offices are furnished is presumed as a free-standing facility, unless CMS determines the facility has provider-based status.

(5) A facility that has requested provider-based status in relation to a hospital or CAH on or after October 1, 2000 and before October 1, 2002 will be treated as provider-based in relation to the hospital or CAH from the first date on or after October 1, 2000 on which the facility was licensed (to the extent required by the State), staffed and equipped to treat patients until the date on which CMS determines that the facility does not qualify for provider-based status.

(c) *Reporting of material changes in relationships.* A main provider that has had one or more facilities or organizations considered provider-based also may report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that would affect the provider-based status of the facility or organization.

(d) *Requirements applicable to all facilities or organizations.* Any facility or organization for which provider-based status is sought, whether located on or off the campus of a potential main provider, must meet all of the following requirements to be determined by CMS to have provider-based status:

(1) *Licensure.* The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS will determine that the facility or organization does not have provider-based status.

(2) *Clinical services.* The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:

(i) Professional staff of the facility or organization have clinical privileges at the main provider.

(ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.

(iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the

same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

(iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.

(v) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.

(vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

(3) *Financial integration.* The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

(4) *Public awareness.* The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

(5) *Obligations of hospital outpatient departments and hospital-based entities.* In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section.

(e) *Additional requirements applicable to off-campus facilities or organizations.* Except as described in paragraphs (b)(2) and (b)(5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

(1) *Operation under the ownership and control of the main provider.* The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

(i) The business enterprise that constitutes the facility or organization is 100 percent owned by the main provider.

(ii) The main provider and the facility or organization seeking status as a department of the main provider, a remote location of a hospital, or a satellite facility have the same governing body.

(iii) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the main provider where it is based.

(iv) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.

(2) *Administration and supervision.* The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that

exists in the relationship between the main provider and one of its existing departments, as evidenced by compliance with all of the following requirements:

(i) The facility or organization is under the direct supervision of the main provider.

(ii) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity—

(A) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

(B) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.

(iii) The following administrative functions of the facility or organization are integrated with those of the provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are—

(A) Contracted out under the same contract agreement; or

(B) Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

(3) *Location*. The facility or organization meets the requirements in paragraph (e)(3)(i), (e)(3)(ii), (e)(3)(iii), (e)(3)(iv), (e)(3)(v), or, in the case of an RHC, paragraph (e)(3)(vi) of this section, and the requirements in paragraph (e)(3)(vii) of this section.

(i) The facility or organization is located within a 35-mile radius of the campus of the hospital or CAH that is the potential main provider.

(ii) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under § 412.106 of this chapter) greater than 11.75 percent or is described in § 412.106(c)(2) of this chapter implementing section 1886(d)(5)(F)(i)(II) of the Act and is—

(A) Owned or operated by a unit of State or local government;

(B) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or

(C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

(iii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period—

(A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider; or

(B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider).

(iv) If the facility or organization is unable to meet the criteria in paragraph (e)(3)(iii)(A) or paragraph (e)(3)(iii)(B) of this section because it was not in operation during all of the

12-month period described in paragraph (e)(3)(iii) of this section, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph (e)(3)(iii) of this section, accounted for at least 75 percent of the patients served by the main provider.

(v) The facility or organization meets all of the following criteria:

(A) The facility or organization is seeking provider-based status with respect to a hospital that meets the criteria in § 412.23(d) for reimbursement under Medicare as a children's hospital;

(B) The facility or organization meets the criteria for identifying intensive care type units set forth in the Medicare reasonable cost reimbursement regulations under § 413.53(d).

(C) The facility or organization accepts only patients who are newborn infants who require intensive care on an inpatient basis.

(D) The hospital in which the facility or organization is physically located is in a rural area as defined in § 412.64(b)(1)(ii)(C) of this chapter.

(E) The facility or organization is located within a 100-mile radius of the children's hospital that is the potential main provider.

(F) The facility or organization is located at least 35 miles from the nearest other neonatal intensive care unit.

(G) The facility or organization meets all other requirements for provider-based status under this section.

(vi) Both of the following criteria are met:

(A) The facility or organization is an RHC that is otherwise qualified as a provider-based entity of a hospital that has fewer than 50 beds, as determined under § 412.105(b) of this chapter; and

(B) The hospital with which the facility or organization has a provider-based relationship is located in a rural area, as defined in § 412.64(b)(1)(ii)(C) of this subchapter.

(vii) A facility or organization may qualify for provider-based status under this section only if the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.

(f) *Provider-based status for joint ventures.* In order for a facility or organization operated as a joint venture to be considered provider-based, the facility or organization must—

(1) Be partially owned by at least one provider'

(2) Be located on the main campus of a provider who is a partial owner;

(3) Be provider-based to that one provider whose campus on which the facility or organization is located; and

(4) Also meet all the requirements applicable to all provider-based facilities and organizations in paragraph (d) of this section. For example, where a provider has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the provider or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based.

(g) *Obligations of hospital outpatient departments and hospital-based entities.* To qualify for provider-based status in relation to a hospital, a facility or organization must comply with the following requirements:

(1) The following departments must comply with the antidumping rules of § 489.20(l), (m), (q), and (r) and § 489.24 of this chapter:

(i) Any facility or organization that is located on the main hospital campus and is treated by Medicare under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by Medicare under this section as a department of the hospital and is a dedicated emergency department, as defined in § 489.24(b) of this chapter.

(2) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined under the rules of Part 414 of this chapter.

(3) Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.

(4) Physicians who work in hospital outpatient departments or hospital-based entities are obligated to comply with the non-discrimination provisions in § 489.10(b) of this chapter.

(5) Hospital outpatient departments (other than RHCs) must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.

(6) In the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based entity, payments for services in the hospital outpatient department or hospital-based entity are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS set forth at § 412.2(c)(5) of this chapter and at § 413.40(c)(2), respectively.

(7) When a Medicare beneficiary is treated in a hospital outpatient department that is not located on the main provider's campus, the treatment is not required to be provided by the antidumping rules in § 489.24 of this chapter, and the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, the following requirements must be met:

(i) The hospital must provide written notice to the beneficiary, before the delivery of services, of—

(A) The amount of the beneficiary's potential financial liability; or

(B) If the exact type and extent of care needed are not known, an explanation that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based, an estimate based on typical or average charges for visits to the facility, and a statement that the patient's actual liability will depend upon the actual services furnished by the hospital.

(ii) The notice must be one that the beneficiary can read and understand.

(iii) If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, before the delivery of services, to the beneficiary's authorized representative.

(iv) In cases where a hospital outpatient department provides examination or treatment that is required to be provided by the antidumping rules of § 489.24 of this chapter, notice, as described in this paragraph (g)(7), must be given as soon as possible after the existence of an emergency has been ruled out or the emergency condition has been stabilized.

(8) Hospital outpatient departments must meet applicable hospital health and safety rules for Medicare-participating hospitals in part 482 of this chapter.

(h) *Management contracts.* A facility or organization that is not located on the campus of the potential main provider and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:

(1) The main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at part 414 of this chapter. Other than staff that may be paid under such a Medicare fee schedule, the main provider may not utilize the services of ''leased'' employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) that are directly involved in the delivery of patient care.

(2) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph (e)(2)(iii) of this section.

(3) The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph (e)(2)(ii) of this section.

(4) The management contract is held by the main provider itself, not by a parent organization that has control

over both the main provider and the facility or organization.

(i) *Furnishing all services under arrangement.* A facility or organization may not qualify for provider-based status if all patient care services furnished at the facility or organization are furnished under arrangements.

(j) *Inappropriate treatment of a facility or organization as provider-based*—(1) *Determination and review.* If CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request a determination of provider-based status from CMS under paragraph (b)(3) of this section and CMS determines that the facility or organization did not meet the requirements for provider-based status under paragraphs (d) through (i) of this section, as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS will—

(i) Issue notice to the provider in accordance with paragraph (j)(3) of this section, adjust the amount of future payments to the provider for services of the facility or organization in accordance with paragraph (j)(4) of this section, and continue payments to the provider for services of the facility or organization only in accordance with paragraph (j)(5) of this section; and

(ii) Except as otherwise provided in paragraphs (b)(2), (b)(5), or (j)(2) of this section, recover the difference between the amount of payments that actually was made and the amount of payments that CMS estimates should have been made, in the absence of compliance with the provider-based requirements, to that provider for services at the facility or organization for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889 of this chapter.

(2) *Exception for good faith effort.* CMS will not recover any payments for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001, if, during all of that period—

(i) The requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(4) of this section were met;

(ii) All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and

(iii) All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described in paragraph (g)(2) of this section.

(3) *Notice to provider.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will issue written notice to the provider that payments for past cost reporting periods may be reviewed and recovered as described in paragraph (j)(1)(ii) of this section, and that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(4) of this section.

(4) *Adjustment of payments.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will adjust future payments to the provider or the facility or organization, or both, to estimate the amounts that would be paid for the same services furnished by a freestanding facility.

(5) *Continuation of payment.* (i) The notice of denial of provider-based status sent to the provider will ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, of whether the provider intends to seek a determination of provider-based status for the facility or organization under this section or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a freestanding facility.

(ii) If the provider indicates that it will not be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payment under this paragraph (j)(5) will end as of the 30th day after the date of notice.

(iii) If the provider indicates that it will be seeking a determination for the

facility or organization under this section or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(4) of this section, for as long as is required for all billing requirements to be met (but not longer than 6 months) if the provider or the facility or organization or its practitioners—

(A) Submits, as applicable, a complete request for a determination of provider-based status or a complete enrollment application and provide all other required information within 90 days after the date of notice; and

(B) Furnishes all other information needed by CMS to make a determination regarding provider-based status or process the enrollment application, as applicable, and verifies that other billing requirements are met.

(v) If the necessary applications or information are not provided, CMS will terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

(k) *Temporary treatment as provider-based.* If a provider submits a complete attestation of compliance with the requirements for provider-based status for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits the attestation and any required supporting documentation until the date that CMS determines that the facility or organization does not meet the provider-based rules. If CMS subsequently determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete attestation of compliance with provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. For purposes of this paragraph (k), a complete attestation of compliance with provider-based requirements is one that includes all information needed to permit CMS to make a determination under paragraph (b)(3) of this section.

(l) *Correction of errors.* (1) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did report to CMS under paragraph (c) of this section, treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.

(2) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and if the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS under paragraph (c) of this section, CMS will take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in paragraphs (j)(3), (j)(4), and (j)(5) of this section, and will recover past payments to the provider to the extent described in paragraph (j)(1)(ii) of this section.

(m) *Status of Indian Health Service and Tribal facilities and organizations.* Facilities and organizations operated by the Indian Health Service or Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if, on or before April 7, 2000, they furnished only services that were billed as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are:

(1) Owned and operated by the Indian Health Service;

(2) Owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act (Pub. L. 93–638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes: or

(3) Owned by the Indian Health Service but leased and operated by the Tribe under the Indian Self-Determination Act (Pub. L. 93–638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes.

(n) *FQHCs and ''look alikes.''* A facility that has, since April 7, 1995, furnished only services that were billed as if they had been furnished by a department of a provider will continue to be treated, for purposes of this section, as a department of the provider without regard to whether it complies with the criteria for provider-based status in this section, if the facility—

(1) Received a grant on or before April 7, 2000 under section 330 of the Public Health Service Act and continues to receive funding under such a grant, or is receiving funding from a grant made on or before April 7, 2000 under section 330 of the Public Health Service Act under a contract with the recipient of such a grant, and continues to meet the requirements to receive a grant under section 330 of the Public Health Service Act; or

(2) Based on the recommendation of the Public Health Service, was determined by CMS on or before April 7, 2000 to meet the requirements for receiving a grant under section 330 of the Public Health Service Act, and continues to meet such requirements.

(o) *Effective date of provider-based status*—(1) *General rule.* Provider-based status for a facility or organization is effective on the earliest date all of the requirements of this part have been met.

(2) *Inappropriate treatment as provider-based or not reporting material change.* Effective for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in paragraph (b)(2) of this section, for cost reporting periods starting on or after July 1, 2003), if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section for those periods, or previously was determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS under paragraph (c) of this section, CMS will not treat the facility or organization as provider-based for payment purposes until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under this part

[65 FR 18538, Apr. 7, 2000, as amended at 65 FR 58920, Oct. 3, 2000; 66 FR 1599, Jan. 9, 2001; 66 FR 59920, Nov. 30, 2001; 67 FR 50114, Aug. 1, 2002; 68 FR 46070, Aug. 4, 2003; 68 FR 53261, Sept. 9, 2003; 70 FR 47487, Aug. 12, 2005]

§ 413.70 Payment for services of a CAH.

(a) *Payment for inpatient services furnished by a CAH (other than services of distinct part units).* (1) Effective for cost reporting periods beginning on or after January 1, 2004, payment for inpatient services of a CAH, other than services of a distinct part unit of the CAH, is 101 percent of the reasonable costs of the CAH in providing CAH services to its inpatients, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in Part 415 of this chapter, except that the following payment principles are excluded when determining payment for CAH inpatient services:

(i) Lesser of cost or charges;

(ii) Ceilings on hospital operating costs;

(iii) Reasonable compensation equivalent (RCE) limits for physician services to providers; and

(iv) The payment window provisions for preadmission services, specified in § 412.2(c)(5) of this subchapter and § 413.40(c)(2).

(2) Except as specified in paragraph (a)(3) of this section, payment to a CAH for inpatient services does not include any costs of physician services or other professional services to CAH inpatients, and is subject to the Part A hospital deductible and coinsurance, as determined under subpart G of part 409 of this chapter.

(3) If a CAH meets the criteria in § 412.113(c) of this subchapter for pass-through of costs of anesthesia services furnished by qualified nonphysician anesthetists employed by the CAH or obtained under arrangements, payment to the CAH for the costs of those services is made in accordance with § 412.113(c).

(4) Payment for inpatient services of distinct part psychiatric or rehabilitation units is described in paragraph (e) of this section.

(b) *Payment for outpatient services furnished by CAH.*

(1) *General.*

(i) Unless the CAH elects to be paid for services to its outpatients under the method specified in paragraph (b)(3) of this section, the amount of payment for outpatient services of a CAH is the amount determined under paragraph (b)(2) of this section.

(ii) Except as specified in paragraph (b)(6) of this section, payment to a CAH for outpatient services does not include any costs of physician services or other professional services to CAH outpatients.

(2) *Reasonable costs for facility services.* (i) Effective for cost reporting periods beginning on or after January 1, 2004, payment for outpatient services of a CAH is 101 percent of the reasonable costs of the CAH in providing CAH services to its outpatients, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in Part 415 of this chapter, except that the following payment principles are excluded when determining payment for CAH outpatient services:

(A) Lesser of cost or charges; and

(B) RCE limits.

(ii) Payment to a CAH under paragraph (b)(2) of this section does not include any costs of physician services or other professional services to CAH outpatients and, other than for clinical diagnostic laboratory tests, is subject to the Part B deductible and coinsurance amounts as determined under §§ 410.152(k), 410.160, and 410.161 of this chapter.

(iii) Payment for outpatient clinical diagnostic laboratory tests is not subject to the Medicare Part B deductible and coinsurance amounts. Payment to a CAH for clinical diagnostic laboratory tests will be made at 101 percent of reasonable cost under this section only if the individuals are outpatients of the CAH, as defined in § 410.2 of this chapter, and are physically present in the CAH, at the time the specimens are collected. Clinical diagnostic laboratory tests performed for persons who are not physically present when the specimens are collected will be made in accordance with the provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Social Security Act.

(3) *Election to be paid 101 percent of reasonable costs for facility services plus fee schedule for professional services.* (i) A CAH may elect to be paid for outpatient services in any cost reporting period beginning on or after July 1, 2004 under the method described in paragraphs (b)(3)(ii) and (b)(3)(iii) of this section.

(A) The election must be made in writing, made on an annual basis, and delivered to the fiscal intermediary servicing the CAH at least 30 days before the start of the cost reporting period for which the election is made.

(B) An election of this payment method, once made for a cost reporting period, remains in effect for all of that period and, effective for cost reporting periods beginning on or after July 1, 2004, applies to all services furnished to outpatients during that period by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with 42 CFR part 424, Subpart F of this chapter. If a physician or other practitioner does not reassign his or her billing rights to the CAH in accordance with 42 CFR part 424, payment for the physician's or practitioner's services to CAH outpatients will be made on a fee schedule or other applicable basis as specified in Subpart B of part 414 of this subchapter.

(C) In the case of a CAH that made an election under this section before November 1, 2003, for a cost reporting period beginning before December 1, 2003, the rules in paragraph (b)(3)(i)(B) of this section are applicable to cost reporting periods beginning on or after July 1, 2001.

(D) An election made under paragraph (b)(3)(i)(B) or paragraph (b)(3)(i)(C) of this section is effective only for a period for which it was made and does not apply to an election that was withdrawn or revoked prior to the start of the cost reporting period for which it was made.

(ii) If the CAH elects payment under this method, payment to the CAH for each outpatient visit will be the sum of the following:

(A) For facility services not including any services for which payment may be made under paragraph (b)(3)(ii)(B) of this section, 101 percent of the reasonable costs of the services as determined under paragraph (b)(2)(i) of this section; and

(B) For professional services that are furnished by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with Part 424, Subpart F of this chapter, and that would otherwise be payable to the physician or other practitioner if the rights to bill for them had not been reassigned, 115 percent of the amounts that otherwise would be paid for the service if the CAH had not elected payment under this method.

(iii) Payment to a CAH, other than for clinical diagnostic laboratory tests, is subject to the Part B deductible and coinsurance amounts, as determined under §§ 410.152(k), 410.160, and 410.161 of this chapter.

(4) *Costs of certain emergency room on-call providers.* (i) Effective for cost reporting periods beginning on or after October 1, 2001, the reasonable costs of outpatient CAH services under paragraph (b) of this section may include amounts for reasonable compensation and related costs for an emergency room physician who is on call but who is not present on the premises of the CAH involved, is not otherwise furnishing physicians' services, and is not on call at any other provider or facility. Effective for costs incurred for services furnished on or after January 1, 2005, the payment amount of 101 percent of the reasonable costs of outpatient CAH services may also include amounts for reasonable compensation and related costs for the following emergency room providers who are on call but who are not present on the premises of the CAH involved, are not otherwise furnishing physicians' services, and are not on call at any other provider or facility: physician assistants, nurse practitioners, and clinical nurse specialists.

(ii) For purposes of this paragraph (b)(4)—

(A) ''Amounts for reasonable compensation and related costs'' means all allowable costs of compensating emergency room physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on call to the extent that the costs are found to be reasonable under the rules specified in paragraph (b)(2) of this section and the applicable sections of Part 413. Costs of compensating these specified medical emergency room staff are allowable only if the costs are incurred under written contracts that require the physician, physician assistant, nurse practitioner, or clinical nurse specialist to come to the CAH when the physician's or other practitioner's presence is medically required.

(B) Effective for costs incurred on or after January 1, 2005, an ''emergency room physician, physician assistant, nurse practitioner, or clinical nurse specialist who is on call'' means a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care who is immediately available by telephone or radio contact, and is available onsite within the timeframes specified in § 485.618(d) of this chapter.

(5) *Costs of ambulance services.*

(i) Effective for services furnished on or after December 21, 2000, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

(ii) For purposes of paragraph (b)(5) of this section, the distance between the CAH or the entity and the other provider or supplier of ambulance services will be determined as the shortest distance in miles measured over improved roads between the CAH or the

entity and the site at which the vehicles of the closest provider or supplier of ambulance services are garaged. An improved road for this purpose is any road that is maintained by a local, State, or Federal government entity and is available for use by the general public. An improved road will be considered to include the paved surface up to the front entrance of the hospital and the front entrance of the garage.

(6) If a CAH meets the criteria in § 412.113(c) of this subchapter for pass-through of costs of anesthesia services furnished by nonphysician anesthetists employed by the CAH or obtained under arrangement, payment to the CAH for the costs of those services is made in accordance with § 412.113(c) of this chapter.

(c) *Final payment based on cost report.* Final payment to the CAH for CAH facility services to inpatients and outpatients furnished during a cost reporting is based on a cost report for that period, as required under § 413.20(b).

(d) *Periodic interim payments.* Subject to the provisions of § 413.64(h), a CAH receiving payments under this section may elect to receive periodic interim payments (PIP) for Part A inpatient CAH services, effective for payments made on or after July 1, 2004. Payment is made biweekly under the PIP method unless the CAH requests a longer fixed interval (not to exceed one month) between payments. The biweekly interim payment amount is based on the total estimated Medicare payment (after estimated beneficiary deductibles and coinsurance) for the cost reporting period. Each payment is made 2 weeks after the end of a biweekly period of service, as described in § 413.64(h)(6). These PIP provisions are further described in § 413.64(h)(6). Under certain circumstances that are described in § 413.64(g), a CAH that is not receiving PIP may request an accelerated payment.

(e) *Payment for service of distinct part psychiatric and rehabilitation units of CAHS.* Payment for inpatient services of distinct part psychiatric units of CAHs—

(1) For cost reporting periods beginning before January 1, 2005, payment is made on a reasonable cost basis, subject to the provisions of § 413.40.

(2) For cost reporting periods beginning on or after January 1, 2005, payment is made in accordance with regulations governing inpatient psychiatric facilities at subpart N (§ 412.400 through § 412.432) of Part 412 of this subchapter.

(3) Payment for inpatient services of distinct part rehabilitation units of CAHs is made in accordance with regulations governing the inpatient rehabilitation facilities prospective payment system at Subpart P (§ 412.600 through § 412.632) of Part 412 of this subchapter.

[65 FR 47109, Aug. 1, 2000, as amended at 66 FR 32195, June 13, 2001; 66 FR 39936, Aug. 1, 2001; 67 FR 50118, Aug. 1, 2002; 68 FR 45471, Aug. 1, 2003; 69 FR 49252, Aug. 11, 2004; 69 FR 66981, Nov. 15, 2004]

§ 413.74 Payment to a foreign hospital.

(a) *Principle.* Section 1814(f) of the Act provides for the payment of emergency and nonemergency inpatient hospital services furnished by foreign hospitals to Medicare beneficiaries. Subpart H of part 424 of this chapter, together with this section, specify the conditions for payment. These conditions may result in payments only to Canadian and Mexican hospitals.

(b) *Amount of payment.* Effective with admissions on or after January 1, 1980, the reasonable cost for services covered under the Medicare program furnished to beneficiaries by a foreign hospital will be equal to 100 percent of the hospital's customary charges (as defined in § 413.13(b)) for the services.

(c) *Submittal of claims.* The hospital must establish its customary charges for the services by submitting an itemized bill with each claim it files in accordance with its election under § 424.104 of this chapter.

(d) *Exchange rate.* Payment to the hospital will be subject to the official exchange rate on the date the patient is discharged and to the applicable deductible and coinsurance amounts described in §§ 409.80 through 409.83.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

Subpart F—Specific Categories of Costs

§ 413.75 Direct GME payments: General requirements.

(a) *Statutory basis and scope*—(1) Basis. This section and §§ 413.76 through 413.83 implement section 1886(h) of the Act by establishing the methodology for Medicare payment of the cost of direct graduate medical educational activities.

(2) *Scope*. This section and §§ 413.76 through 413.83 apply to Medicare payments to hospitals and hospital-based providers for the costs of approved residency programs in medicine, osteopathy, dentistry, and podiatry for cost reporting periods beginning on or after July 1, 1985.

(b) *Definitions*. For purposes of this section and §§ 413.76 through 413.83, the following definitions apply:

''*All or substantially all of the costs for the training program in the nonhospital setting*'' means the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education (GME).

Approved geriatric program means a fellowship program of one or more years in length that is approved by one of the national organizations listed in § 415.152 of this chapter under that respective organization's criteria for geriatric fellowship programs.

Approved medical residency program means a program that meets one of the following criteria:

(1) Is approved by one of the national organizations listed in § 415.152 of this chapter.

(2) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(i) The Directory of Graduate Medical Education Programs published by the American Medical Association, and available from American Medical Association, Department of Directories and Publications, 515 North State Street, Chicago, Illinois 60610; or

(ii) The Annual Report and Reference Handbook published by the American Board of Medical Specialties, and available from American Board of Medical Specialties, One Rotary Center, Suite 805, Evanston, Illinois 60201.

(3) Is approved by the Accreditation Council for Graduate Medical Education (ACGME) as a fellowship program in geriatric medicine.

(4) Is a program that would be accredited except for the accrediting agency's reliance upon an accreditation standard that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether the standard provides exceptions or exemptions.

Base period means a cost reporting period that began on or after October 1, 1983 but before October 1, 1984.

Community support means funding that is provided by the community and generally includes all non-Medicare sources of funding (other than payments made for furnishing services to individual patients), including State and local government appropriations. Community support does not include grants, gifts, and endowments of the kind that are not to be offset in accordance with section 1134 of the Act.

CPI-U stands for the Consumer Price Index for All Urban Consumers as compiled by the Bureau of Labor Statistics.

Foreign medical graduate means a resident who is not a graduate of a medical, osteopathy, dental, or podiatry school, respectively, accredited or approved as meeting the standards necessary for accreditation by one of the following organizations:

(1) The Liaison Committee on Medical Education of the American Medical Association.

(2) The American Osteopathic Association.

(3) The Commission on Dental Accreditation.

(4) The Council on Podiatric Medical Education.

FMGEMS stands for the Foreign Medical Graduate Examination in the Medical Sciences (Part I and Part II).

FTE stands for full-time equivalent.

GME stands for graduate medical education.

Medicare GME affiliated group means—

(1) Two or more hospitals that are located in the same urban or rural area (as those terms are defined in Subpart D of Part 412 of this subchapter.

(2) Two or more hospitals that are not located in the same or in a contiguous urban or rural area, but meet the rotation requirement in § 413.79(g)(2), and are jointly listed—

(i) As the sponsor, primary clinical site, or major participating institution for one or more programs as these terms are used in the most current publication of the *Graduate Medical Education Directory;* or

(ii) As the sponsor or is listed under ''affiliations and outside rotations'' for one or more programs in operation in *Opportunities, Directory of Osteopathic Postdoctoral Education Programs*.

(3) Two or more hospitals that are under common ownership and, effective for all Medicare GME affiliation agreements beginning July 1, 2003, meet the rotation requirement in § 413.79(g)(2).

Medicare GME affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in a Medicare GME affiliated group, as defined in this section, that specifies—

(1) The term of the Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year;

(2) Each participating hospital's direct and indirect GME FTE caps in effect prior to the Medicare GME affiliation;

(3) The total adjustment to each hospital's FTE caps in each year that the Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect FTE caps that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount;

(4) The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's FTE caps (in accordance with paragraph (3) of this definition); and

(5) The names of the participating hospitals and their Medicare provider numbers.

Medicare patient load means, with respect to a hospital's cost reporting period, the total number of hospital inpatient days during the cost reporting period that are attributable to patients for whom payment is made under Medicare Part A divided by total hospital inpatient days. In calculating inpatient days, inpatient days in any distinct part of the hospital furnishing a hospital level of care are included and nursery days are excluded.

Primary care resident is a resident enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine or osteopathic general practice.

Redistribution of costs occurs when a hospital counts FTE residents in medical residency programs and the costs of the program had previously been incurred by an educational institution.

Resident means an intern, resident, or fellow who participates in an approved medical residency program, including programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board.

Rural track FTE limitation means the maximum number of residents (as specified in § 413.79(l)) training in a rural track residency program that an urban hospital may include in its FTE count and that is in addition to the number of FTE residents already included in the hospital's FTE cap.

Rural track or integrated rural track means an approved medical residency training program established by an urban hospital in which residents train for a portion of the program at the urban hospital and then rotate for a portion of the program to a rural hospital(s) or a rural nonhospital site(s).

Shared rotational arrangement means a residency training program under which a resident(s) participates in training at two or more hospitals in that program.

(c) *Payment for GME costs—General rule.* Beginning with cost reporting periods starting on or after July 1, 1985, hospitals, including hospital-based providers, are paid for the costs of approved GME programs as described in §§ 413.76 through 413.83.

(d) *Documentation requirements.* To include a resident in the FTE count for a particular cost reporting period, the hospital must furnish the following information. The information must be certified by an official of the hospital and, if different, an official responsible for administering the residency program.

(1) The name and social security number of the resident.

(2) The type of residency program in which the individual participates and the number of years the resident has completed in all types of residency programs.

(3) The dates the resident is assigned to the hospital and any hospital-based providers.

(4) The dates the resident is assigned to other hospitals, or other freestanding providers, and any nonprovider setting during the cost reporting period, if any.

(5) The name of the medical, osteopathic, dental, or podiatric school from which the resident graduated and the date of graduation.

(6) If the resident is an FMG, documentation concerning whether the resident has satisfied the requirements of this section.

(7) The name of the employer paying the resident's salary.

[69 FR 49254, Aug. 11, 2004, as amended at 70 FR 47489, Aug. 12, 2005]

§ 413.76 Direct GME payments: Calculation of payments for GME costs.

A hospital's Medicare payment for the costs of an approved residency program is calculated as follows:

(a) *Step one.* The hospital's updated per resident amount (as determined under § 413.77) is multiplied by the actual number of FTE residents (as determined under § 413.79). This result is the aggregate approved amount for the cost reporting period.

(b) *Step two.* The product derived in step one is multiplied by the hospital's Medicare patient load.

(c) *Step three.* For portions of cost reporting periods occurring on or after January 1, 1998, the product derived in step one is multiplied by the proportion of the hospital's inpatient days attributable to individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 of the Act and who are entitled to Medicare Part A or with a Medicare+Choice organization under Title XVIII, Part C of the Act. This amount is multiplied by an applicable payment percentage equal to—

(1) 20 percent for 1998;

(2) 40 percent for 1999;

(3) 60 percent in 2000;

(4) 80 percent in 2001; and

(5) 100 percent in 2002 and subsequent years.

(d) *Step four.* Effective for portions of cost reporting periods occurring on or after January 1, 2000, the product derived from step three is reduced by a percentage equal to the ratio of the Medicare+Choice nursing and allied health payment ''pool'' for the current calendar year as described at § 413.87(f), to the projected total Medicare+Choice direct GME payments made to all hospitals for the current calendar year.

(e) *Step five.* (1) For portions of cost reporting periods beginning on or after January 1, 1998 and before January 1, 2000, add the results of steps two and three.

(2) Effective for portions of cost reporting periods beginning on or after January 1, 2000, add the results of steps two and four.

(f) *Step six.* The product derived in step two is apportioned between Part A and Part B of Medicare based on the ratio of Medicare's share of reasonable costs excluding GME costs attributable to each part as determined through the Medicare cost report.

[69 FR 49254, Aug. 11, 2004]

§ 413.77 Direct GME payments: Determination of per resident amounts.

(a) *Per resident amount for the base period*—(1) Except as provided in paragraph (d) of this section, the intermediary determines a base-period per resident amount for each hospital as follows:

(i) Determine the allowable GME costs for the cost reporting period beginning on or after October 1, 1983 but before October 1, 1984. In determining these costs, GME costs allocated to the nursery cost center, research and other nonreimbursable cost centers, and hospital-based providers that are not participating in Medicare are excluded and GME costs allocated to distinct-part hospital units and hospital-based providers that participate in Medicare are included.

(ii) Divide the costs calculated in paragraph (a)(1)(i) of this section by the average number of FTE residents working in all areas of the hospital complex (including those areas whose costs were excluded under paragraph (a)(1)(i) of this section) for its cost reporting period beginning on or after October 1, 1983 but before October 1, 1984.

(2) In determining the base-period per resident amount under paragraph (a)(1) of this section, the intermediary—

(i) Verifies the hospital's base-period GME costs and the hospital's average number of FTE residents;

(ii) Excludes from the base-period GME costs any nonallowable or misclassified costs, including those previously allowed under § 412.113(b)(3) of this chapter; and

(iii) Upon a hospital's request, includes GME costs that were misclassified as operating costs during the hospital's prospective payment base year and were not allowable under § 412.113(b)(3) of this chapter during the GME base period. These costs may be included only if the hospital requests an adjustment of its prospective payment hospital-specific rate or target amount as described in § 413.82(a) of this chapter.

(3) If the hospital's cost report for its GME base period is no longer subject to reopening under § 405.1885 of this chapter, the intermediary may modify the hospital's base-period costs solely for purposes of computing the per resident amount.

(4) If the intermediary modifies a hospital's base-period GME costs as described in paragraph (a)(2)(ii) of this section, the hospital may request an adjustment of its prospective payment hospital-specific rate or target amount as described in § 413.82(a) of this chapter.

(5) The intermediary notifies each hospital that either had direct GME costs or received indirect education payment in its cost reporting period beginning on or after October 1, 1984, and before October 1, 1985, of its base-period average per resident amount. A hospital may appeal this amount within 180 days of the date of that notice.

(b) *Per resident amount for cost reporting periods beginning on or after July 1, 1985, and before July 1, 1986.* For cost reporting periods beginning on or after July 1, 1985, and before July 1, 1986, a hospital's base-period per resident amount is adjusted as follows:

(1) If a hospital's base period began on or after October 1, 1983, and before July 1, 1984, the amount is adjusted by the percentage change in the CPI-U that occurred between the hospital's base period and the first cost reporting period to which the provisions of this section apply. The adjusted amount is then increased by one percent.

(2) If a hospital's base period began on or after July 1, 1984 and before October 1, 1984, the amount is increased by one percent.

(c) *Per resident amount for cost reporting periods beginning on or after July 1, 1986.* Subject to the provisions of paragraph (d) of this section, for cost reporting periods beginning on or after July 1, 1986, a hospital's base-period per resident amount is adjusted as follows:

(1) Except as provided in paragraph (c)(2) of this section, each hospital's per resident amount for the previous cost reporting is adjusted by the projected change in the CPI-U for the 12-month cost reporting period. This adjustment is subject to revision during the settlement of the cost report to reflect actual changes in the CPI-U that occurred during the cost reporting period.

(2) For cost reporting periods beginning on or after October 1, 1993 through September 30, 1995, each hospital's per resident amount for the previous cost reporting period will not be adjusted for any resident FTEs who are not either a primary care resident or an obstetrics and gynecology resident.

(d) *Per resident amount for cost reporting periods beginning on or after October*

1, 2000 and ending on or before September 30, 2013. For cost reporting periods beginning on or after October 1, 2000 and ending on or before September 30, 2013, a hospital's per resident amount for each fiscal year is adjusted in accordance with the following provisions:

(1) *General provisions.* For purposes of this § 413.77—

(i) *Weighted average per resident amount.* The weighted average per resident amount is established as follows:

(A) Using data from hospitals' cost reporting periods ending during FY 1997, CMS calculates each hospital's single per resident amount by adding each hospital's primary care and nonprimary care per resident amounts, weighted by its respective FTEs, and dividing by the sum of the FTEs for primary care and nonprimary care residents.

(B) Each hospital's single per resident amount calculated under paragraph (d)(1)(i)(A) of this section is standardized by the 1999 geographic adjustment factor for the physician fee schedule area (as determined under § 414.26 of this chapter) in which the hospital is located.

(C) CMS calculates an average of all hospitals' standardized per resident amounts that are determined under paragraph (d)(1)(i)(B) of this section. The resulting amount is the weighted average per resident amount.

(ii) *Primary care/obstetrics and gynecology and nonprimary care per resident amounts.* A hospital's per resident amount is an amount inclusive of any CPI-U adjustments that the hospital may have received since the hospital's base year, including any CPI-U adjustments the hospital may have received because the hospital trains primary care/obstetrics and gynecology residents and nonprimary care residents as specified under paragraph (c)(2) of this section.

(2) *Adjustment beginning in FY 2001 and ending in FY 2013.* For cost reporting periods beginning on or after October 1, 2000, and ending on or before September 30, 2013, a hospital's per resident amount is adjusted in accordance with paragraphs (d)(2)(i) through (d)(2)(iv) of this section, in that order:

(i) *Updating the weighted average per resident amount for inflation.* The weighted average per resident amount (as determined under paragraph (d)(1)(i) of this section) is updated by the estimated percentage increase in the CPI-U during the period beginning with the month that represents the midpoint of the cost reporting periods ending during FY 1997 (that is, October 1, 1996) and ending with the midpoint of the hospital's cost reporting period that begins in FY 2001.

(ii) *Adjusting for locality.* The updated weighted average per resident amount determined under paragraph (d)(2)(i) of this section (the national average per resident amount) is adjusted for the locality of each hospital by multiplying the national average per resident amount by the 1999 geographic adjustment factor for the physician fee schedule area in which each hospital is located, established in accordance with § 414.26 of this chapter.

(iii) *Determining necessary revisions to the per resident amount.* The locality-adjusted national average per resident amount, as calculated in accordance with paragraph (d)(2)(ii) of this section, is compared to the hospital's per resident amount and is revised, if appropriate, according to the following three categories:

(A) *Floor.* (*1*) For cost reporting periods beginning on or after October 1, 2000, and before October 1, 2001, if the hospital's per resident amount would otherwise be less than 70 percent of the locality-adjusted national average per resident amount for FY 2001 (as determined under paragraph (d)(2)(ii) of this section), the per resident amount is equal to 70 percent of the locality-adjusted national average per resident amount for FY 2001.

(*2*) For cost reporting periods beginning on or after October 1, 2001, and before October 1, 2002, if the hospital's per resident amount would otherwise be less than 85 percent of the locality-adjusted national average per resident amount for FY 2002 (as determined under paragraph (d)(2)(ii) of this section), the per resident amount is equal to 85 percent of the locality-adjusted national average per resident amount for FY 2002.

(*3*) For subsequent cost reporting periods beginning on or after October 1, 2002, the hospital's per resident amount

is updated using the methodology specified under paragraph (c)(1) of this section.

(B) *Ceiling*. If the hospital's per resident amount is greater than 140 percent of the locality-adjusted national average per resident amount, the per resident amount is adjusted as follows for FY 2001 through FY 2013:

(*1*) *FY 2001*. For cost reporting periods beginning on or after October 1, 2000 and on or before September 30, 2001, if the hospital's FY 2000 per resident amount exceeds 140 percent of the FY 2001 locality-adjusted national average per resident amount (as calculated under paragraph (d)(2)(ii) of this section), subject to the provision stated in paragraph (d)(2)(iii)(B)(*5*) of this section, the hospital's per resident amount is frozen at the FY 2000 per resident amount and is not updated for FY 2001 by the CPI-U factor.

(*2*) *FY 2002*. For cost reporting periods beginning on or after October 1, 2001, and on or before September 30, 2002, if the hospital's FY 2001 per resident amount exceeds 140 percent of the FY 2002 locality-adjusted national average per resident amount, subject to the provision stated in paragraph (d)(2)(iii)(B)(*5*) of this section, the hospital's per resident amount is frozen at the FY 2001 per resident amount and is not updated for FY 2002 by the CPI-U factor.

(*3*) *FY 2003*. For cost reporting periods beginning on or after October 1, 2002, and on or before September 30, 2003, if the hospital's per resident amount for the previous cost reporting period is greater than 140 percent of the locality-adjusted national average per resident amount for that same previous cost reporting period (for example, for cost reporting periods beginning in FY 2003, compare the hospital's per resident amount from the FY 2002 cost report to the hospital's locality-adjusted national average per resident amount from FY 2002), subject to the provision stated in paragraph (d)(2)(iii)(B)(*5*) of this section, the hospital's per resident amount is adjusted using the methodology specified in paragraph (c)(1) of this section, except that the CPI-U applied for a 12-month period is reduced (but not below zero) by 2 percentage points.

(*4*) *FY 2004 through FY 2013*. For cost reporting periods beginning on or after October 1, 2003, and on or before September 30, 2013, if the hospital's preceding year per resident amount exceeds 140 percent of the current year's locality-adjusted national average per resident amount (as calculated under paragraph (d)(2)(ii) of this section), subject to the provision stated in paragraph (d)(2)(iii)(B)(*5*) of this section, the hospital-specific per resident amount is frozen for the current year at the preceding year's hospital-specific per resident amount and is not updated by the CPI-U factor.

(*5*) *General rule for hospitals that exceed the ceiling*. For cost reporting periods beginning on or after October 1, 2000, and on or before September 30, 2013, if a hospital's per resident amount exceeds 140 percent of the hospital's locality-adjusted national average per resident amount and it is adjusted under any of the criteria under paragraphs (d)(2)(iii)(B)(*1*) through (d)(2)(iii)(B)(*3*) of this section, the current year per resident amount cannot be reduced below 140 percent of the locality-adjusted national average per resident amount.

(C) *Per resident amounts greater than or equal to the floor and less than or equal to the ceiling*. For cost reporting periods beginning on or after October 1, 2000 and on or before September 30, 2013, if a hospital's per resident amount is greater than or equal to 70 percent and less than or equal to 140 percent of the hospital's locality-adjusted national average per resident amount for each respective fiscal year, the hospital's per resident amount is updated using the methodology specified in paragraph (c)(1) of this section.

(e) *Exceptions*—(1) *Base period for certain hospitals*. If a hospital did not have any approved medical residency training programs or did not participate in Medicare during the base period, but either condition changes in a cost reporting period beginning on or after July 1, 1985, the intermediary establishes a per resident amount for the hospital using the information from the first cost reporting period during which the hospital participates in Medicare and the residents are on duty during the first month of that period.

Any GME program costs incurred by the hospital before that cost reporting period are reimbursed on a reasonable cost basis. The per resident amount is based on the lower of the amount specified in paragraph (e)(1)(i) or in paragraph (e)(1)(ii) of this section, subject to the provisions of paragraph (e)(1)(iii) of this section.

(i) The hospital's actual costs, incurred in connection with the GME program for the hospital's first cost reporting period in which residents were on duty during the first month of the cost reporting period.

(ii) Except as specified in paragraph (e)(1)(iii)of this section—

(A) For base periods that begin before October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area, as that term is used in the prospective payment system under Part 412 of this chapter.

(B) For base periods beginning on or after October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(iii) If, under paragraph (e)(1)(ii)(A) or paragraph (e)(1)(ii)(B) of this section, there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter.

(2) *Short or long base-period cost reporting periods.* If a hospital's base-period cost reporting period reflects GME costs for a period that is shorter than 50 weeks or longer than 54 weeks, the intermediary converts the allowable costs for the base period into a daily figure. The daily figure is then multiplied by 365 or 366, as appropriate, to derive the approved per resident amount for a 12-month base-period cost reporting period. If a hospital has two cost reporting periods beginning in the base period, the later period serves as the base-period cost reporting period.

(3) *Short or long cost reporting periods beginning on or after July 1, 1985.* If a hospital's cost reporting period is shorter than 50 weeks or longer than 54 weeks, the hospital's intermediary should contact CMS Central Office to receive a special CPI-U adjustment factor.

(f) *Residency match.* Effective for portions of cost reporting periods beginning on or after October 1, 2004, with respect to a resident who matches simultaneously for a first year of training in a primary care specialty, and for an additional year(s) of training in a nonprimary care specialty, the per resident amount that is used to determine direct GME payment with respect to that resident is the nonprimary care per resident amount for the first year of training in the primary care specialty and for the duration of the resident's training in the nonprimary care specialty.

(g) *Special use of locality-adjusted national average per resident amount.* Effective for portions of cost reporting periods beginning on or after July 1, 2005, for a hospital that counts additional residents as a result of an increase in its FTE resident cap under § 413.79(c)(4) direct GME payments attributable to those additional FTE residents are calculated using the locality-adjusted national average per resident amount, as determined under paragraph (d)(2)(ii) of this section. The hospital will receive direct GME payments based on the sum of the following two direct GME calculations:

(1) A calculation using the per resident amount(s) as determined under paragraph (d) of this section and the hospital's number of FTE residents that is not attributable to an FTE resident cap increase under § 413.79(c)(4); and

(2) A calculation using the locality-adjusted national average per resident amount, as determined under paragraph (d)(2)(ii) of this section, inflated to the hospital's current cost reporting period, and the hospital's number of FTE residents that is attributable to

the increase in the hospital's FTE resident cap under § 413.79(c)(4).

[69 FR 49254, Aug. 11, 2004, as amended at 69 FR 60252, Oct. 7, 2004; 70 FR 47489, Aug. 12, 2005]

§ 413.78 Direct GME payments: Determination of the total number of FTE residents.

Subject to the weighting factors in §§ 413.79 and 413.80, and subject to the provisions of § 413.81, the count of FTE residents is determined as follows:

(a) Residents in an approved program working in all areas of the hospital complex may be counted.

(b) No individual may be counted as more than one FTE. A hospital cannot claim the time spent by residents training at another hospital. Except as provided in paragraphs (c), (d), and (e) of this section, if a resident spends time in more than one hospital or in a nonprovider setting, the resident counts as partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

(c) On or after July 1, 1987, and for portions of cost reporting periods occurring before January 1, 1999, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs is not excluded in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities.

(2) There is a written agreement between the hospital and the outside entity that states that the resident's compensation for training time spent outside of the hospital setting is to be paid by the hospital.

(d) For portions of cost reporting periods occurring on or after January 1, 1999, and before October 1, 2004, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities.

(2) The written agreement between the hospital and the nonhospital site must indicate that the hospital will incur the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(3) The hospital must incur all or substantially all of the costs for the training program in the nonhospital setting in accordance with the definition in § 413.75(b).

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

(e) For portions of cost reporting periods occurring on or after October 1, 2004, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities.

(2) The hospital must incur all or substantially all of the costs of the training program in a nonhospital setting(s) (in accordance with the definition under § 413.75(b)).

(3) The hospital must comply with one of the following:

(i) The hospital must pay all or substantially all of the costs of the training program in a nonhospital setting(s) attributable to training that occurs during a month by the end of the third month following the month in which the training in the nonhospital site occurred; or

(ii) There is a written agreement between the hospital and the nonhospital site that states that the hospital will incur the cost of the resident's salary

and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

[69 FR 49254, Aug. 11, 2004]

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

Subject to the provisions in § 413.80, CMS determines a hospital's number of FTE residents by applying a weighting factor to each resident and then summing the resulting numbers that represent each resident. The weighting factor is determined as follows:

(a) *Initial residency period*. Generally, for purposes of this section, effective July 1, 1995, an initial residency period is defined as the minimum number of years required for board eligibility.

(1) Prior to July 1, 1995, the initial residency period equals the minimum number of years required for board eligibility in a specialty or subspecialty plus 1 year. An initial residency period may not exceed 5 years in order to be counted toward determining FTE status except in the case of a resident in an approved geriatric program whose initial residency period may last up to 2 additional years.

(2) Effective October 1, 2003, for a resident who trains in an approved geriatric program that requires the residents to complete 2 years of training to initially become board eligible in the geriatric specialty, the 2 years spent in the geriatrics program are treated as part of the resident's initial residency period.

(3) Effective July 1, 2000, for residency programs that began before, on, or after November 29, 1999, the period of board eligibility and the initial residency period for a resident in an approved child neurology program is the period of board eligibility for pediatrics plus 2 years.

(4) Effective August 10, 1993, residents or fellows in an approved preventive medicine residency or fellowship program also may be counted as a full FTE resident for up to 2 additional years beyond the initial residency period limitations.

(5) For combined residency programs, an initial residency period is defined as the time required for individual certification in the longer of the programs. If the resident is enrolled in a combined medical residency training program in which all of the individual programs (that are combined) are for training primary care residents (as defined in § 413.75(b)) or obstetrics and gynecology residents, the initial residency period is the time required for individual certification in the longer of the programs plus 1 year.

(6) For residency programs other than those specified in paragraphs (a)(2) through (a)(4) of this section, the initial residency period is the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training, as specified in the most recently published edition of the Graduate Medical Education Directory.

(7) For residency programs in osteopathy, dentistry, and podiatry, the minimum requirement for certification in a specialty or subspecialty is the minimum number of years of formal training necessary to satisfy the requirements of the appropriate approving body listed in § 415.152 of this chapter.

(8) For residency programs in geriatric medicine, accredited by the appropriate approving body listed in § 415.152 of this chapter, these programs are considered approved programs on the later of—

(i) The starting date of the program within a hospital; or

(ii) The hospital's cost reporting periods beginning on or after July 1, 1985.

(9) The time spent in residency programs that do not lead to certification in a specialty or subspecialty, but that otherwise meet the definition of approved programs, as described in § 413.75(b), is counted toward the initial residency period limitation.

(10) Effective for portions of cost reporting periods beginning on or after

October 1, 2004, if a hospital can document that a resident simultaneously matched for one year of training in a particular specialty program, and for a subsequent year(s) of training in a different specialty program, the resident's initial residency period will be determined based on the period of board eligibility for the specialty associated with the program for which the resident matched for the subsequent year(s) of training. Effective for portions of cost reporting periods beginning on or after October 1, 2005, if a hospital can document that a particular resident, prior to beginning the first year of residency training, matched in a specialty program for which training would begin at the conclusion of the first year of training, that resident's initial residency period will be determined in the resident's first year of training based on the period of board eligibility associated with the specialty program for which the resident matched for subsequent training year(s).

(b) *Weighting factor*—(1) If the resident is in an initial residency period, the weighting factor is one.

(2) If the resident is not in an initial residency period, the weighting factor is 1.00 during the period beginning on or after July 1, 1985 and before July 1, 1986, .75 during the period beginning on or after July 1, 1986 and before July 1, 1987, and .50 thereafter without regard to the hospital's cost reporting period.

(c) *Unweighted FTE counts.*

(1) *Definitions.* As used in this paragraph (c):

(i) *Otherwise applicable resident cap* refers to a hospital's FTE resident cap that is determined for a particular cost reporting period under paragraph (c)(2) of this section.

(ii) *Reference resident level* refers to a hospital's resident level in the applicable reference period specified under paragraph (c)(3)(ii) of this section.

(iii) *Resident level* refers to the number of unweighted allopathic and osteopathic FTE residents who are training in a hospital in a particular cost reporting period.

(2) *Determination of the FTE resident cap.* Subject to the provisions of paragraphs (c)(3) through (c)(6) of this section and § 413.81, for purposes of determining direct GME payment—

(i) For cost reporting periods beginning on or after October 1, 1997, a hospital's resident level may not exceed the hospital's unweighted FTE count (or, effective for cost reporting periods beginning on or after April 1, 2000, 130 percent of the unweighted FTE count for a hospital located in a rural area) for these residents for the most recent cost reporting period ending on or before December 31, 1996.

(ii) If a hospital's number of FTE residents in a cost reporting period beginning on or after October 1, 1997, and before October 1, 2001, exceeds the limit described in this section, the hospital's total weighted FTE count (before application of the limit) will be reduced in the same proportion that the number of FTE residents for that cost reporting period exceeds the number of FTE residents for the most recent cost reporting period ending on or before December 31, 1996.

(iii) If the hospital's number of FTE residents in a cost reporting period beginning on or after October 1, 2001 exceeds the limit described in this section, the hospital's weighted FTE count (before application of the limit) for primary care and obstetrics and gynecology residents and nonprimary care residents, respectively, will be reduced in the same proportion that the number of FTE residents for that cost reporting period exceeds the number of FTE residents for the most recent cost reporting period ending on or before December 31, 1996.

(iv) Hospitals that are part of the same Medicare GME affiliated group (as described under § 413.75(b)) may elect to apply the limit on an aggregate basis as described under paragraph (f) of this section.

(v) The fiscal intermediary may make appropriate modifications to apply the provisions of this paragraph (c) of this section based on the equivalent of a 12-month cost reporting period.

(3) *Determination of the reduction to the FTE resident cap due to unused FTE resident slots.* If a hospital's reference resident level is less than its otherwise applicable FTE resident cap as determined under paragraph (c)(2) of this

section or paragraph (e) of this section in the reference cost reporting period (as described under paragraph (c)(3)(ii) of this section), for portions of cost reporting periods beginning on or after July 1, 2005, the hospital's otherwise applicable FTE resident cap is reduced by 75 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level. Under this provision—

(i) *Exemption for certain rural hospitals.* A rural hospital, as defined at subpart D of part 412 of this subchapter, with less than 250 beds (as determined at § 412.105(b)) in its most recent cost reporting period ending on or before September 30, 2002, is exempt from any reduction to the otherwise applicable FTE resident cap limit under paragraph (c)(3) of this section.

(ii) *Reference cost reporting periods.*

(A) To determine a hospital's reference resident level, CMS uses one of the following periods:

(*1*) A hospital's most recent cost reporting period ending on or before September 30, 2002, for which a cost report has been settled or if the cost report has not been settled, the as-submitted cost report (subject to audit); or

(*2*) A hospital's cost reporting period that includes July 1, 2003 if the hospital submits a timely request to CMS to increase its resident level due to an expansion of an existing program and that expansion is not reflected on the hospital's most recent settled cost report. An expansion of an existing program means that, except for expansions due to newly approved programs under paragraph (c)(3)(ii)(A)(*3*) of this section, the number of unweighted allopathic and osteopathic FTE residents in any cost reporting period after the hospital's most recent settled cost report, up to and including the hospital's cost report that includes July 1, 2003, is greater than the number of unweighted allopathic and osteopathic FTE residents in programs that were existing at that hospital during the hospital's most recent settled cost report.

(*3*) A hospital may submit a timely request that CMS adjust the resident level for purposes of determining any reduction under paragraph (c)(3) of this section for the following purposes:

(*i*) In the hospital's reference cost reporting period under paragraph (c)(3)(ii)(A)(*1*) of this section, to include the number of FTE residents for which a new program was accredited by the appropriate allopathic or osteopathic accrediting body (listed under § 415.152 of this chapter) before January 1, 2002, if the program was not in operation during the reference cost reporting period under paragraph (c)(3)(ii)(A)(*1*); or

(*ii*) In the hospital's reference cost reporting period under paragraph (c)(3)(ii)(A)(*2*) of this section, to include the number of FTE residents for which a new program was accredited by the appropriate allopathic or osteopathic accrediting body (listed under § 415.152 of this chapter) before January 1, 2002, if the program was not in operation during the cost reporting period that includes July 1, 2003, and if the hospital also qualifies to use its cost report under paragraph (c)(3)(ii)(A)(*2*) of this section due to an expansion of an existing program.

(B) If the cost report that is used to determine a hospital's otherwise applicable FTE resident cap in the reference period is not equal to 12 months, the fiscal intermediary may make appropriate modifications to apply the provisions of paragraph (c)(3)(i)(A) of this section based on the equivalent of a 12-month cost reporting period.

(iii) If the new program described in paragraph (c)(3)(ii)(A)(3)(i) or paragraph (c)(3)(ii)(A)(ii) was accredited for a range of residents, the hospital may request that its reference resident level in its applicable reference cost reporting period under paragraph (c)(3)(ii)(A)(*1*) or (c)(3)(ii)(A)(*2*) of this section be adjusted to reflect the maximum number of accredited slots applicable to that hospital.

(iv) *Consideration of Medicare GME affiliated group agreements.* For hospitals that are members of the same affiliated group for the program year July 1, 2003 through June 30, 2004, in determining whether a hospital's otherwise applicable resident FTE resident cap is reduced under paragraph(c)(3) of this section, CMS treats these hospitals as a group. Using information from the hospitals' cost reports that include July 1, 2003, if the hospitals' aggregate FTE resident counts are equal to or

greater than the aggregate otherwise applicable FTE resident cap for the affiliated group, then no reductions are made under paragraph (c)(3) of this section to the hospitals' otherwise applicable FTE resident caps. If the hospitals' aggregate FTE resident count is below the aggregate otherwise applicable FTE resident cap, then CMS determines on a hospital-specific basis whether the individual hospital's FTE resident count is less than its otherwise applicable resident cap (as adjusted by affiliation agreement(s)) in the hospital's cost report that includes July 1, 2003. If the hospital's FTE resident count is in excess of its otherwise applicable FTE resident cap, the hospital will not have its otherwise applicable FTE resident cap reduced under paragraph (c)(3) of this section. Hospitals in the affiliated group that have FTE resident counts below their individual otherwise applicable FTE resident caps are subject to a pro rata reduction in their otherwise applicable FTE resident caps that is equal, in total, to 75 percent of the difference between the aggregate FTE cap and the aggregate FTE count for the affiliated group. The pro rata reduction to the individual hospital's otherwise applicable resident cap is calculated by dividing the difference between the hospital's individual otherwise applicable FTE resident cap and the hospital's FTE resident count by the total amount by which all of the hospitals' individual FTE resident counts are below their otherwise affiliated FTE resident caps, multiplying the quotient by the difference between the aggregate FTE resident cap and the aggregate FTE resident counts for the affiliated group, and multiplying that result by 75 percent.

(4) *Determination of an increase in otherwise applicable resident cap.* For portions of cost reporting periods beginning on or after July 1, 2005, a hospital may receive an increase in its otherwise applicable FTE resident cap up to an additional 25 FTEs (as determined by CMS) if the hospital meets the requirements and qualifying criteria of section 1886(h)(7) of the Act and implementing instructions issued by CMS and if the hospital submits an application to CMS within the timeframe specified by CMS.

(5) *Special rules for hospitals that participate in demonstration projects or voluntary resident reduction plans.*

(i) If a hospital was participating in a demonstration project under section 402 of Pubic Law 90–248 or the voluntary reduction plan under § 413.88 for a greater period of time than the time period that elapsed since it withdrew from participation (or if it completed its participation) in the demonstration program or the voluntary reduction plan, for purposes of determining a possible reduction to the FTE resident caps under paragraph (c)(3) of this section, CMS compares the higher of the hospital's base number of residents (after subtracting any dental and podiatric FTE residents) or the hospital's reference resident level to the hospital's otherwise applicable resident cap determined under paragraph (c)(2) of this section.

(ii) If a hospital participated in the demonstration project or the voluntary resident reduction plan for a period of time that is less than the time that elapsed since it withdraw from participation in the demonstration project or the voluntary reduction plan, the special rules in paragraph (c)(5)(i) do not apply, and the hospital is subject to the procedures applicable to all other hospitals for determining possible reductions to the FTE resident caps under paragraph (c)(3) of this section.

(iii) CMS will not redistribute residency positions that are attributable to a hospital's participation in a demonstration project or a voluntary resident reduction plan to other hospitals that seek to increase their FTE resident caps under paragraph (c)(4) of this section.

(6) *FTE resident caps for rural hospitals that are redesignated as urban.* A rural hospital redesignated as urban after September 30, 2004, as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, may retain the increases to its FTE resident cap that it received under paragraphs (c)(2)(i), (e)(1)(iii), and (e)(3) of this section while it was located in a rural area.

(d) *Weighted FTE counts.* Subject to the provisions of § 413.81, for purposes of determining direct GME payment—

(1) For the hospital's first cost reporting period beginning on or after October 1, 1997, the hospital's weighted FTE count is equal to the average of the weighted FTE count for the payment year cost reporting period and the preceding cost reporting period.

(2) For cost reporting periods beginning on or after October 1, 1998, and before October 1, 2001, the hospital's weighted FTE count is equal to the average of the weighted FTE count for the payment year cost reporting period and the preceding two cost reporting periods.

(3) For cost reporting periods beginning on or after October 1, 2001, the hospital's weighted FTE count for primary care and obstetrics and gynecology residents is equal to the average of the weighted primary care and obstetrics and gynecology counts for the payment year cost reporting period and the preceding two cost reporting periods, and the hospital's weighted FTE count for nonprimary care residents is equal to the average of the weighted nonprimary care FTE counts for the payment year cost reporting period and the preceding two cost reporting periods.

(4) The fiscal intermediary may make appropriate modifications to apply the provisions of this paragraph (d) based on the equivalent of 12-month cost reporting periods.

(5) If a hospital qualifies for an adjustment to the limit established under paragraph (c)(2) of this section for new medical residency programs created under paragraph (e) of this section, the count of the residents participating in new medical residency training programs above the number included in the hospital's FTE count for the cost reporting period ending during calendar year 1996 is added after applying the averaging rules in this paragraph (d), for a period of years. Residents participating in new medical residency training programs are included in the hospital's FTE count before applying the averaging rules after the period of years has expired. For purposes of this paragraph (d), for each new program started, the period of years equals the minimum accredited length for each new program. The period of years begins when the first resident begins training in each new program.

(6) Subject to the provisions of paragraph (h) of this section, FTE residents that are displaced by the closure of either another hospital or another hospital's program are added to the FTE count after applying the averaging rules in this paragraph (d), for the receiving hospital for the duration of the time that the displaced residents are training at the receiving hospital.

(7) Subject to the provisions under paragraph (k) of this section, effective for cost reporting periods beginning on or after April 1, 2000, FTE residents in a rural track program at an urban hospital are included in the urban hospital's rolling average calculation described in this paragraph (d).

(e) *New medical residency training programs.* If a hospital establishes a new medical residency training program as defined in paragraph (l) of this section on or after January 1, 1995, the hospital's FTE cap described under paragraph (c) of this section may be adjusted as follows:

(1) If a hospital had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it establishes a new medical residency training program on or after January 1, 1995, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted based on the product of the highest number of residents in any program year during the third year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program.

(i) If the residents are spending an entire program year (or years) at one hospital and the remainder of the program at another hospital, the adjustment to each respective hospital's cap is equal to the product of the highest number of residents in any program year during the third year of the first

program's existence and the number of years the residents are training at each respective hospital.

(ii) Prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's residency program(s), the hospital's cap may be adjusted during each of the first 3 years of the hospital's new residency program using the actual number of residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(iii) Except for rural hospitals, the cap will not be adjusted for new programs established more than 3 years after the first program begins training residents.

(iv) An urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap only if the adjustment that results from the affiliation is an increase to the urban hospital's FTE cap.

(v) A rural hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap.

(2) If a hospital had allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, the hospital's unweighted FTE cap may be adjusted for new medical residency training programs established on or after January 1, 1995 and on or before August 5, 1997. The adjustment to the hospital's FTE resident limit for the new program is based on the product of the highest number of residents in any program year during the third year of the newly established program and the number of years in which residents are expected to complete each program based on the minimum accredited length for the type of program.

(i) If the residents are spending an entire program year (or years) at one hospital and the remainder of the program at another hospital, the adjustment to each respective hospital's cap is equal to the product of the highest number of residents in any program year during the third year of the first program's existence and the number of years the residents are training at each respective hospital.

(ii) Prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's residency program, the hospital's cap may be adjusted during each of the first 3 years of the hospital's new residency program, using the actual number of residents in the new programs. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(3) If a hospital with allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, is located in a rural area (or other hospitals located in rural areas that added residents under paragraph (e)(1) of this section), the hospital's unweighted FTE limit may be adjusted in the same manner described in paragraph (e)(2) of this section to reflect the increase for residents in the new medical residency training programs established after August 5, 1997. For these hospitals, the limit will be adjusted for additional new programs but not for expansions of existing or previously existing programs.

(4) A hospital seeking an adjustment to the limit on its unweighted resident count policy must provide documentation to its fiscal intermediary justifying the adjustment.

(f) *Medicare GME affiliated group.* A hospital may receive a temporary adjustment to its FTE cap, which is subject to the averaging rules under paragraph (e)(3) of this section, to reflect residents added or subtracted because the hospital is participating in a Medicare GME affiliated group (as defined under §413.75(b)). Under this provision—

(1) Each hospital in the Medicare GME affiliated group must submit the Medicare GME affiliation agreement, as defined under §413.75(b) of this section, to the CMS fiscal intermediary servicing the hospital and send a copy to CMS's Central Office no later than July 1 of the residency program year

during which the Medicare GME affiliation agreement will be in effect.

(2) Each hospital in the Medicare GME affiliated group must have a shared rotational arrangement, as defined in § 413.75(b), with at least one other hospital within the Medicare GME affiliated group, and all of the hospitals within the Medicare GME affiliated group must be connected by a series of such shared rotational arrangements.

(3) During the shared rotational arrangements under a Medicare GME affiliation agreement, as defined in § 413.75(b), more than one of the hospitals in the Medicare GME affiliated group must count the proportionate amount of the time spent by the resident(s) in its FTE resident counts. No resident may be counted in the aggregate as more than one FTE.

(4) The net effect of the adjustments (positive or negative) on the Medicare GME affiliated hospitals' aggregate FTE cap for each Medicare GME affiliation agreement must not exceed zero.

(5) If the Medicare GME affiliation agreement terminates for any reason, the FTE cap of each hospital in the Medicare GME affiliated group will revert to the individual hospital's pre-affiliation FTE cap that is determined under the provisions of paragraph (c) of this section.

(g) *Newly constructed hospitals.* A hospital that began construction of its facility prior to August 5, 1997, and sponsored new medical residency training programs on or after January 1, 1995, and on or before August 5, 1997, that either received initial accreditation by the appropriate accrediting body or temporarily trained residents at another hospital(s) until the facility was completed, may receive an adjustment to its FTE cap.

(1) The newly constructed hospital's FTE cap is equal to the lesser of—

(i) The product of the highest number of residents in any program year during the third year of the newly established program and the number of years in which residents are expected to complete the programs based on the minimum accredited length for each type of program; or

(ii) The number of accredited slots available to the hospital for each year of the programs.

(2) If the new medical residency training programs sponsored by the newly constructed hospital have been in existence for 3 years or more by the time the residents begin training at the newly constructed hospital, the newly constructed hospital's cap will be based on the number of residents training in the third year of the programs begun at the temporary training site.

(3) If the new medical residency training programs sponsored by the newly constructed hospital have been in existence for less than 3 years by the time the residents begin training at the newly constructed hospital, the newly constructed hospital's cap will be based on the number of residents training at the newly constructed hospital in the third year of the programs (including the years at the temporary training site).

(4) A hospital that qualifies for an adjustment to its FTE cap under this paragraph (g) may be part of an affiliated group for purposes of establishing an aggregate FTE cap.

(5) The provisions of this paragraph (g) are applicable during portions of cost reporting periods occurring on or after October 1, 1999.

(h) *Closure of hospital or hospital residency program.*

(1) *Definitions.* For purposes of this section—

(i) *Closure of a hospital* means the hospital terminates its Medicare agreement under the provisions of § 489.52 of this chapter.

(ii) *Closure of a hospital residency training program* means the hospital ceases to offer training for residents in a particular approved medical residency training program.

(2) *Closure of a hospital.* A hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of another hospital's closure if the hospital meets the following criteria:

(i) The hospital is training additional residents from a hospital that closed on or after July 1, 1996.

(ii) No later than 60 days after the hospital begins to train the residents,

the hospital submits a request to its fiscal intermediary for a temporary adjustment to its FTE cap, documents that the hospital is eligible for this temporary adjustment by identifying the residents who have come from the closed hospital and have caused the hospital to exceed its cap, and specifies the length of time the adjustment is needed.

(3) *Closure of a hospital's residency training program.* If a hospital that closes its residency training program voluntarily agrees to temporarily reduce its FTE cap according to the criteria specified in paragraph (h)(3)(ii) of this section, another hospital(s) may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of the residency training program if the criteria specified in paragraph (h)(3)(i) of this section are met.

(i) *Receiving hospital(s).* A hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of another hospital's residency training program if—

(A) The hospital is training additional residents from the residency training program of a hospital that closed a program; and

(B) No later than 60 days after the hospital begins to train the residents, the hospital submits to its fiscal intermediary a request for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the residents who have come from another hospital's closed program and have caused the hospital to exceed its cap, specifies the length of time the adjustment is needed, and submits to its fiscal intermediary a copy of the FTE reduction statement by the hospital that closed its program, as specified in paragraph (h)(3)(ii)(B) of this section.

(ii) *Hospital that closed its program(s).* A hospital that agrees to train residents who have been displaced by the closure of another hospital's program may receive a temporary FTE cap adjustment only if the hospital with the closed program—

(A) Temporarily reduces its FTE cap based on the FTE residents in each program year training in the program at the time of the program's closure. This yearly reduction in the FTE cap will be determined based on the number of those residents who would have been training in the program during that year had the program not closed; and

(B) No later than 60 days after the residents who were in the closed program begin training at another hospital, submit to its fiscal intermediary a statement signed and dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the hospital training the displaced residents to obtain a temporary adjustment to its cap; identifies the residents who were in training at the time of the program's closure; identifies the hospitals to which the residents are transferring once the program closes; and specifies the reduction for the applicable program years.

(i) *Additional FTEs for residents on maternity or disability leave or other approved leave of absence.* Effective for cost reporting periods beginning on or after November 29, 1999, a hospital may receive an adjustment to its FTE cap of up to three additional resident FTEs, if the hospital meets the following criteria:

(1) The additional residents are residents of a primary care program that would have been counted by the hospital as residents for purposes of the hospital's FTE cap but for the fact that the additional residents were on maternity or disability leave or a similar approved leave of absence during the hospital's most recent cost reporting period ending on or before December 31, 1996;

(2) The leave of absence was approved by the residency program director to allow the residents to be absent from the program and return to the program after the leave of absence; and

(3) No later than 6 months after August 1, 2000, the hospital submits to the fiscal intermediary a request for an adjustment to its FTE cap, and provides contemporaneous documentation of the approval of the leave of absence by the residency director, specific to each additional resident that is to be counted for purposes of the adjustment.

(j) *Residents previously trained at VA hospitals.* For cost reporting periods beginning on or after October 1, 1997, a non-Veterans Affairs (VA) hospital may receive a temporary adjustment to its FTE cap to reflect residents who had previously trained at a VA hospital and were subsequently transferred to the non-VA hospital, if that hospital meets the following criteria:

(1) The transferred residents had been training previously at a VA hospital in a program that would have lost its accreditation by the ACGME if the residents continued to train at the VA hospital;

(2) The residents were transferred to the hospital from the VA hospital on or after January 1, 1997, and before July 31, 1998; and

(3) The hospital submits a request to its fiscal intermediary for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the residents who have come from the VA hospital, and specifies the length of time those residents will be trained at the hospital.

(k) *Residents training in rural track programs.* Subject to the provisions of § 413.81, an urban hospital that establishes a new residency program, or has an existing residency program, with a rural track (or an integrated rural track) may include in its FTE count residents in those rural tracks, in addition to the residents subject to its FTE cap specified under paragraph (c) of this section. An urban hospital with a rural track residency program may count residents in those rural tracks up to a rural track FTE limitation if the hospital complies with the conditions specified in paragraphs (k)(2) through (k)(7) of this section.

(1) If an urban hospital rotates residents to a separately accredited rural track program at a rural hospital(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count for the time the rural track residents spend at the urban hospital. The urban hospital may include in its FTE count those residents in the rural track training at the urban hospital, not to exceed its rural track FTE limitation, determined as follows:

(i) For the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital.

(ii) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital or the rural hospital(s) and are designated at the beginning of their training to be rotated to the rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2002, or for more than one-half of the duration of the program effective for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital.

(2) If an urban hospital rotates residents to a separately accredited rural track program at a rural nonhospital site(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track FTE limitation, determined as follows:

(i) For the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonhospital site(s).

(ii) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(A) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at—

(*1*) The urban hospital and are designated at the beginning of their training to be rotated to a rural nonhospital site(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(*2*) The rural nonhospital site(s); and

(B) The number of years in which the residents are expected to complete each program based on the minimum accredited length for the type of program.

(3) If an urban hospital rotates residents in the rural track program to a rural hospital(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the rural hospital may not include those residents in its FTE count (if the rural track is not a new program under paragraph (e)(3) of this section, or if the rural hospital's FTE count exceeds that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation.

(4) If an urban hospital rotates residents in the rural track program to a rural nonhospital site(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under §413.78(d). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(i) For the first 3 years of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonhospital site(s).

(ii) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(A) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at the rural nonhospital site(s) or are designated at the beginning of their training to be rotated to the rural nonhospital site(s) for a period that is less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2002, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(B) The length of time in which the residents are being training at the rural nonhospital site(s) only.

(5) All urban hospitals that wish to count FTE residents in rural tracks, not to exceed their respective rural track FTE limitation, must also comply with all of the following conditions:

(i) An urban hospital may not include in its rural track FTE limitation or (assuming the urban hospital's FTE count exceeds its FTE cap) FTE count residents who are training in a rural track residency program that were already included as part of the hospital's FTE cap.

(ii) The hospital must base its count of residents in a rural track on written contemporaneous documentation that each resident enrolled in a rural track program at the hospital intends to rotate for a portion of the residency program to a rural area.

(iii) All residents that are included by the hospital as part of its rural track FTE count (not to exceed its rural track FTE limitation) must train in the rural area. However, where a

resident begins to train in the rural track program at the urban hospital but leaves the program before completing the total required portion of training in the rural area, the urban hospital may count the time the resident trained in the urban hospital if another resident fills the vacated FTE slot and completes the training in the rural portion of the rural track program. An urban hospital may not receive GME payment for the time the resident trained at the urban hospital if another resident fills the vacated FTE slot and first begins to train at the urban hospital.

(6) If CMS finds that residents who are included by the urban hospital as part of its FTE count did not actually complete the training in the rural area, CMS will reopen the urban hospital's cost report within the 3-year reopening period as specified in § 405.1885 of this chapter and adjust the hospital's Medicare GME payments (and, where applicable, the hospital's rural track FTE limitation).

(l) For purposes of this section, a new medical residency training program means a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.

(7) If an urban hospital had established a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent census data and implementation of the new labor market area definitions announced by OMB on June 6, 2003, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) for the rural track programs established prior to the adoption of such new labor market area definitions. In order to receive an adjustment to its FTE resident cap for a new rural track residency program, the urban hospital must establish a rural track program with hospitals that are designated rural based on the most recent geographical location designations adopted by CMS.

[69 FR 49254, Aug. 11, 2004, as amended at 69 FR 60252, Oct. 7, 2004; 69 FR 78530, Dec. 30, 2004; 70 FR 47489, Aug. 12, 2005]

§ 413.80 Direct GME payments: Determination of weighting factors for foreign medical graduates.

(a) The weighting factor for a foreign medical graduate is determined under the provisions of § 413.79 if the foreign medical graduate—

(1) Has passed FMGEMS; or

(2) Before July 1, 1986, received certification from, or passed an examination of, the Educational Committee for Foreign Medical Graduates.

(b) Before July 1, 1986, the weighting factor for a foreign medical graduate is 1.0 times the weight determined under the provisions of § 413.79. On or after July 1, 1986, and before July 1, 1987, the weighting factor for a graduate of a foreign medical school who was in a residency program both before and after July 1, 1986 but who does not meet the requirements set forth in paragraph (a) of this section is .50 times the weight determined under the provisions of § 413.79.

(c) On or after July 1, 1987, these foreign medical graduates are not counted in determining the number of FTE residents.

(d) During the cost reporting period in which a foreign medical graduate passes FMGEMS, the weighting factor for that resident is determined under the provisions of § 413.79 for the part of the cost reporting period beginning with the month the resident passes the test.

(e) On or after September 1, 1989, the National Board of Medical Examiners Examination, Parts I and II, may be substituted for FMGEMS for purposes of the determination made under paragraphs (a) and (d) of this section.

(f) On or after June 1, 1992, the United States Medical Licensing Examination may be substituted for the FMGEMS for purposes of the determination made under paragraphs (a) and (d) of this section. On or after July 1, 1993, only the results of steps I and II of the United States Medical Licensing Examination

will be accepted for purposes of making this determination.

[69 FR 49254, Aug. 11, 2004]

§ 413.81 Direct GME payments: Application of community support and redistribution of costs in determining FTE resident counts.

(a) For purposes of determining direct GME payments, the following principles apply:

(1) *Community support*. If the community has undertaken to bear the costs of medical education through community support, the costs are not considered GME costs to the hospital for purposes of Medicare payment.

(2) *Redistribution of costs*. The costs of training residents that constitute a redistribution of costs from an educational institution to the hospital are not considered GME costs to the hospital for purposes of Medicare payment.

(b) *Application*. A hospital must continuously incur costs of direct GME of residents training in a particular program at a training site since the date the residents first began training in that program in order for the hospital to count the FTE residents in accordance with the provisions of §§ 413.78, 413.79 (c) through (e), and 413.79(k). This rule also applies to providers that are paid for direct GME in accordance with § 405.2468 of this chapter, § 422.270 of this subchapter, and § 413.70.

(c)(1) *Effective date*. Subject to the provisions of paragraph (c)(2) of this section, payments made in accordance with determinations made under the provisions of paragraphs (a) and (b) of this section will be effective for portions of cost reporting periods occurring on or after October 1, 2003.

(2) *Applicability for certain hospitals*. With respect to an FTE resident who begins training in a residency program on or before October 1, 2003, and with respect to whom there has been a redistribution of costs or community support determined under the provisions of paragraphs (a) and (b) of this section, the hospital may continue to count the FTE resident until the resident has completed training in that program, or until 3 years after the date the resident began training in that program, whichever comes first.

[69 FR 49254, Aug. 11, 2004]

§ 413.82 Direct GME payments: Special rules for States that formerly had a waiver from Medicare reimbursement principles.

(a) Effective for cost reporting periods beginning on or after January 1, 1986, hospitals in States that, prior to becoming subject to the prospective payment system, had a waiver for the operation of a State reimbursement control system under section 1886(c) of the Act, section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1 or section 222(a) of the Social Security Amendment of 1972 (42 U.S.C. 1395b–1 (note)) are permitted to change the order in which they allocate administrative and general costs to the order specified in the instructions for the Medicare cost report.

(b) For hospitals making this election, the base-period costs for the purpose of determining the per resident amount are adjusted to take into account the change in the order by which they allocate administrative and general costs to interns and residents in approved program cost centers.

(c) Per resident amounts are determined for the base period and updated as described in § 413.77. For cost reporting periods beginning on or after January 1, 1986, payment is made based on the methodology described in § 413.76.

[69 FR 49254, Aug. 11, 2004]

§ 413.83 Direct GME payments: Adjustment of a hospital's target amount or prospective payment hospital-specific rate.

(a) *Misclassified operating costs*—(1) *General rule*. If a hospital has its base-period GME costs reduced under § 413.77(a) of this section because those costs included misclassified operating costs, the hospital may request that the intermediary review the classification of the affected costs in its rate-of-increase ceiling or prospective payment base year for purposes of adjusting the hospital's target amount or hospital-specific rate. For those cost reports that are not subject to reopening under § 405.1885 of this chapter, the

hospital's reopening request must explicitly state that the review is limited to this one issue.

(2) *Request for review.* The hospital must request review of the classification of its rate-of-increase ceiling or prospective payment base year costs no later than 180 days after the date of the notice by the intermediary of the hospital's base-period average per resident amount. A hospital's request for review must include sufficient documentation to demonstrate to the intermediary that adjustment of the hospital's hospital-specific rate or target amount is warranted.

(3) *Effect of intermediary's review.* If the intermediary, upon review of the hospital's costs, determines that the hospital's hospital-specific rate or target amount should be adjusted, the adjustment of the hospital-specific rate or the target amount is effective for the hospital's cost reporting periods subject to the prospective payment system or the rate-of-increase ceiling that are still subject to reopening under § 405.1885 of this chapter.

(b) *Misclassification of GME costs*—(1) *General rule.* If costs that should have been classified as GME costs were treated as operating costs during both the GME base period and the rate-of-increase ceiling base year or prospective payment base year and the hospital wishes to receive benefit for the appropriate classification of these costs as GME costs in the GME base period, the hospital must request that the intermediary review the classification of the affected costs in the rate-of-increase ceiling or prospective payment base year for purposes of adjusting the hospital's target amount or hospital-specific rate. For those cost reports that are not subject to reopening under § 405.1885 of this chapter, the hospital's reopening request must explicitly state that the review is limited to this one issue.

(2) *Request for review.* The hospital must request review of the classification of its costs no later than 180 days after the date of the intermediary's notice of the hospital's base-period average per resident amount. A hospital's request for review must include sufficient documentation to demonstrate to the intermediary that modification of the adjustment of the hospital's hospital-specific rate or target amount is warranted.

(3) *Effect of intermediary's review.* If the intermediary, upon review of the hospital's costs, determines that the hospital's hospital-specific rate or target amount should be adjusted, the adjustment of the hospital-specific rate and the adjustment of the target amount is effective for the hospital's cost reporting periods subject to the prospective payment system or the rate-of-increase ceiling that are still subject to reopening under § 405.1885 of this chapter.

[69 FR 49254, Aug. 11, 2004]

§ 413.85 Cost of approved nursing and allied health education activities.

(a) *Statutory basis.* This section implements section 1861(v)(1)(A) of the Act and section 4004(b) of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508) by establishing the methodology for Medicare payment of the costs of approved nursing and allied health education activities.

(b) *Scope.* (1) This section sets forth the rules for determining Medicare payments to hospitals for the costs of nursing and allied health education activities.

(2) This section does not address Medicare payments for the direct and indirect costs of graduate medical education (that is, approved residency programs in medicine, osteopathy, dentistry, and podiatry). Medicare payment for these costs is determined as provided in § 412.105 of this subchapter and§§ 413.75 through 413.83.

(3) The rules under this section do not apply to activities that are specified in paragraph (h) of this section and identified as normal operating costs.

(c) *Definitions.* For purposes of this section, the following definitions apply:

Approved educational activities means formally organized or planned programs of study of the type that:

(1) Are operated by providers as specified in paragraph (f) of this section;

(2) Enhance the quality of inpatient care at the provider; and

(3) Meet the requirements of paragraph (e) of this section for State licensure or accreditation.

Classroom instruction costs are those costs associated with formal, didactic instruction on a specific topic or subject in a class that meets at regular, scheduled intervals over a specific time period (for example, semester or quarter), and for which a student receives a grade.

Clinical training costs means costs of training for the acquisition and use of the skills of a nursing or allied health profession or trade in the actual environment in which these skills will be used by the student upon graduation. Clinical training may involve occasional or periodic meetings to discuss or analyze cases, critique performance, or discuss specific skills or techniques; it involves no classroom instruction.

Community support means funding that is provided by the community and generally includes all non-Medicare sources of funding (other than payments made for furnishing services to individual patients), including State and local government appropriations. Community support does not include grants, gifts, and endowments of the kind that are not to be offset in accordance with section 1134 of the Act.

Redistribution of costs means an attempt by a provider to increase the amount, or to expand the types, of the costs of educational activities that are allowed for Medicare payment purposes by claiming costs that previously were not claimed by the provider and were considered costs of an educational institution. For example, costs for a school of nursing or allied health education or a medical school that were incurred by an educational institution and were not allowable to the provider in its prospective payment or rate-of-increase limit base year cost report, or graduate medical education per resident amount calculated under §§ 413.75 through 413.83, are not allowable costs in subsequent fiscal years.

(d) *General payment rules.* (1) Payment for a provider's net cost of nursing and allied health education activities is determined on a reasonable cost basis, subject to the following conditions and limitations:

(i) An approved educational activity—

(A) Is recognized by a national approving body or State licensing authority as specified in paragraph (e) of this section;

(B) Meets the criteria specified in paragraph (f) of this section for identification as an operator of an approved education program.

(C) Enhances the quality of inpatient care at the provider.

(ii) The cost for certain nonprovider-operated programs are reimbursable on a reasonable cost basis if the programs meet the criteria specified in paragraph (g)(2) of this section.

(iii) The costs of certain nonprovider-operated programs at wholly owned subsidiary educational institutions are reimbursable on a reasonable cost basis if the provisions of paragraph (g)(3) of this section are met.

(2) *Determination of net cost.* (i) Subject to the provisions of paragraph (d)(2)(iii) of this section, the net cost of approved educational activities is determined by deducting the revenues that a provider receives from tuition and student fees from the provider's total allowable educational costs that are directly related to approved educational activities.

(ii) A provider's total allowable educational costs are those costs incurred by the provider for trainee stipends, compensation of teachers, and other costs of the activities as determined under the Medicare cost-finding principles in § 413.24. These costs do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support.

(iii) The net costs of approved certified registered nurse anesthetist (CRNA) education programs that are determined on a reasonable cost basis are subject to the additional condition that allowable compensation costs for faculty members who are CRNAs are limited to the compensation costs for administrative activities related to the educational program, the compensation costs directly related to hours spent in classroom instruction, and the costs related to the clinical training of students for which the CRNA may not receive payment under the CRNA fee

schedule. No pass-through compensation costs are allowable for the time a CRNA spends in the clinical training of a student anesthetist during a surgical procedure in the operating room for which the CRNA may receive payment under the CRNA fee schedule. As specified at § 414.46 of this chapter, if the CRNA continuously supervises the services of a single student nurse anesthetist, or where the medical direction rules allow a CRNA to bill for the service, payment can be made under the CRNA fee schedule.

(iv) Net costs are subject to apportionment for Medicare utilization as described in § 413.50.

(e) *Approved nursing and allied health education programs.* CMS will consider an activity an approved nursing and allied health education program if the program is a planned program of study that is licensed by State law, or if licensing is not required, is accredited by the recognized national professional organization for the particular activity. Such national accrediting bodies include, but are not limited to, the Commission on Accreditation of Allied Health Education Programs, the National League of Nursing Accrediting Commission, the Association for Clinical Pastoral Education Inc., and the American Dietetic Association.

(f) *Criteria for identifying programs operated by a provider.* (1) Except as provided in paragraph (f)(2) of this section, for cost reporting periods beginning on or after October 1, 1983, in order to be considered the operator of an approved nursing or allied health education program, a provider must meet all of the following requirements:

(i) Directly incur the training costs.

(ii) Have direct control of the program curriculum. (A provider may enter into an agreement with an educational institution to furnish basic academic courses required for completion of the program, but the provider must provide all of the courses relating to the theory and practice of the nursing or allied health profession involved that are required for the degree, diploma, or certificate awarded at the completion of the program.)

(iii) Control the administration of the program, including collection of tuition (where applicable), control the maintenance of payroll records of teaching staff or students, or both (where applicable), and be responsible for day-to-day program operation. (A provider may contract with another entity to perform some administrative functions, but the provider must maintain control over all aspects of the contracted functions.)

(iv) Employ the teaching staff.

(v) Provide and control both classroom instruction and clinical training (where classroom instruction is a requirement for program completion), subject to the parenthetical sentence in paragraph (f)(1)(ii) of this section.

(2) Absent evidence to the contrary, the provider that issues the degree, diploma, or other certificate upon successful completion of an approved education program is assumed to meet all of the criteria set forth in paragraph (f)(1) of this section and to be the operator of the program.

(g) *Payment for certain nonprovider-operated programs.* (1) *Payment rule.* Costs incurred by a provider, or by an educational institution that is related to the provider by common ownership or control (that is, a related organization as defined in § 413.17(b)), for the clinical training of students enrolled in an approved nursing or allied health education program that is not operated by the provider, are paid on a reasonable cost basis if the conditions specified in paragraph (g)(2) of this section are met.

(2) *Criteria for identification of nonprovider-operated education programs.* Payment for the incurred costs of educational activities identified in paragraph (g)(1) of this section will be made if the following conditions are met:

(i) The clinical training must occur on the premises of the provider, that is, in the hospital itself or in the physical area immediately adjacent to the provider's main buildings, or in other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings.

(ii) The provider must have claimed and been paid for clinical training costs on a reasonable cost basis during the most recent cost reporting period that ended on or before October 1, 1989. This condition is met if a notice of program reimbursement (NPR) was issued

for that cost reporting period by November 5, 1990, and the clinical training costs were included as pass-through costs. If an NPR was not issued by that date, or an NPR was issued but did not treat the clinical training costs as pass-through costs, the condition is met if—

(A) The intermediary included the clinical training costs in the allowable costs used to determine the interim rate for the most recent cost reporting period ending on or before October 1, 1989; or

(B) The provider claimed the clinical training costs as pass-through costs when the cost report for the most recent cost reporting period ending on or before October 1, 1989, was initially submitted.

(iii) In any cost reporting period, the percentage of total allowable provider cost attributable to allowable clinical training cost does not exceed the percentage of total cost for clinical training in the provider's most recent cost reporting period ending on or before October 1, 1989.

(iv) The students in the educational program must provide a benefit to the provider through the provision of clinical services to patients of the provider.

(v) The clinical training costs must be incurred by the provider or by an educational institution related to the provider by common control or ownership as defined in § 413.17(b) (''*Cost to related organizations*.'') Costs incurred by a third-party, regardless of its relationship to either the provider or the educational institution, are not allowed.

(vi) The costs incurred by a provider does not exceed the costs the provider would have incurred if it was the sole operator of the program.

(3) *Special rule: Payment for certain nonprovider-operated programs at wholly owned subsidiary educational institutions.* (i) Effective for portions of cost reporting periods occurring on or after October 1, 2003, a provider that incurs costs for a nursing or allied health education program(s) where those program(s) had originally been provider-operated according to the criteria at paragraph (f) of this section, and then operation of the program(s) was transferred to a wholly owned subsidiary educational institution in order to meet accreditation standards prior to October 1, 2003, and where the provider has continuously incurred the costs of both the classroom and clinical training portions of the program(s) at the educational institution, may receive reasonable cost payment for such a program(s) according to the specifications under paragraphs (g)(3)(ii) and (g)(3)(iii) of this section.

(ii) Payment for the incurred costs of educational activities identified in paragraph (g)(3)(i) of this section will be made on a reasonable cost basis if a provider, as described in paragraph (g)(3)(i) of this section, received Medicare reasonable cost payment for those nursing and allied health education program(s) both prior and subsequent to the date the provider transferred operation of the program(s) to its wholly owned subsidiary educational institution (and ceased to be a provider-operated program(s) according to the criteria under paragraph (f) of this section).

(iii) The provider that meets the requirements in paragraphs (g)(3)(i) and (g)(3)(ii) of this section will be eligible to receive payment under this paragraph for: (A) the clinical training costs incurred for the program(s) as described in paragraph (g)(3)(i) of this section; and (B) classroom costs, but only those costs incurred by the provider for the courses that were included in the programs.

(h) *Cost of educational activities treated as normal operating costs.* The costs of the following educational activities incurred by a provider but not operated by that provider are recognized only as normal operating costs and paid in accordance with the reimbursement principles specified in Part 412 of this subchapter. They include:

(1) Orientation and on-the-job training.

(2) Part-time education for bona fide full-time employees at properly accredited academic or technical institutions (including other providers) devoted to undergraduate or graduate work.

(3) Educational seminars, workshops, and continuing education programs in which the employees participate that enhance the quality of medical care or operating efficiency of the provider

and, effective October 1, 2003, do not lead to the ability to practice and begin employment in a nursing or allied health specialty.

(4) Maintenance of a medical library.

(5) Training of a patient or patient's family in the use of medical appliances or other treatments.

(6) Except as provided in paragraph (g) of this section, clinical training and classroom instruction of students enrolled in an educational program that is not operated by the provider. The following are clinical training and classroom instruction costs that are allowable as normal operating costs:

(i) Costs incurred in the clinical training of students, including the clinical training or clerkship of undergraduate medical school students that takes place in a provider.

(ii) Classroom instruction costs incurred by a provider that meet the following criteria:

(A) The provider's support does not constitute a redistribution of nonprovider costs to the provider. The support must be in addition to the costs already being incurred by the nonprovider-operated program. If the nonprovider entity reduces its costs due to receiving provider support, this reduction constitutes a redistribution of costs from an educational institution to a patient care institution and is a nonallowable provider cost.

(B) The provider receives a benefit for the support it furnishes.

(C) The cost of the provider's support is less than the cost the provider would incur were it to operate the program.

(7) Other activities that do not involve the actual operation of an approved educational program.

[66 FR 3374, Jan. 12, 2001, as amended at 66 FR 14342, Mar. 12, 2001; 68 FR 45471, Aug. 1, 2003; 69 FR 49254, Aug. 11, 2004]

§ 413.87 Payments for Medicare+Choice nursing and allied health education programs.

(a) *Statutory basis.* This section implements section 1886(l) of the Act, which provides for additional payments to hospitals that operate and receive Medicare reasonable cost reimbursement for approved nursing and allied health education programs and the methodology for determining the additional payments.

(b) *Scope.* This section sets forth the rules for determining an additional payment amount to hospitals that receive payments for the costs of operating approved nursing or allied health education programs under § 413.85.

(c) *Qualifying conditions for payment.*

(1) For portions of cost reporting periods occurring on or after January 1, 2000 and before January 1, 2001, a hospital that operates and receives payment for a nursing or allied health education program under § 413.85 may receive an additional payment amount associated with Medicare+Choice utilization. The hospital may receive the additional payment amount, which is calculated in accordance with the provisions of paragraph (d) of this section, if both of the conditions specified in paragraphs (c)(1)(i) and (c)(1)(ii) of this section are met.

(i) The hospital must have received Medicare reasonable cost payment for an approved nursing or allied health education program under § 413.85 in its cost reporting period(s) ending in the fiscal year that is 2 years prior to the current calendar year. (For example, if the current year is calendar year 2000, the fiscal year that is 2 years prior to calendar year 2000 is FY 1998.) For a hospital that first establishes a nursing or allied health education program after FY 1998 and receives reasonable cost payment for the program as specified under § 413.85 after FY 1998, the hospital is eligible to receive an additional payment amount in a calendar year that is 2 years after the respective fiscal year so long as the hospital also meets the condition under paragraph (c)(1(ii) of this section.

(ii) The hospital must be receiving reasonable cost payment for an approved nursing or allied health education program under § 413.85 in the current calendar year.

(2) For portions of cost reporting periods occurring on or after January 1, 2001, in addition to meeting the conditions specified in paragraphs (c)(1)(i) and (c)(1)(ii) of this section, the hospital must have had a Medicare+Choice utilization greater than zero in its cost reporting period(s) ending in the fiscal

year that is 2 years prior to the current calendar year.

(d) *Calculating the additional payment amount for portions of cost reporting periods occurring on or after January 1, 2000 and before January 1, 2001.* For portions of cost reporting periods occurring on or after January 1, 2000 and before January 1, 2001, subject to the provisions of § 413.76(d)(4) relating to calculating a proportional reduction in Medicare+Choice direct GME payments, the additional payment amount specified in paragraph (c) of this section is calculated according to the following steps:

(1) *Step one.* Each calendar year, determine the hospital's total nursing and allied health education program payments from its cost reporting period(s) ending in the fiscal year that is 2 years prior to the current calendar year.

(2) *Step two.* Determine the ratio of the hospital's payments from step one to the total of all nursing and allied health education program payments across all hospitals for all cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year.

(3) *Step three.* Multiply the ratio calculated in step two by the Medicare+Choice nursing and allied health payment ''pool'' determined in accordance with paragraph (f) of this section for the current calendar year. The resulting product is each respective hospital's additional payment amount.

(e) *Calculating the additional payment amount for portions of cost reporting periods occurring on or after January 1, 2001.* For portions of cost reporting periods occurring on or after January 1, 2001, subject to the provisions of § 413.76(d) relating to calculating a proportional reduction in Medicare+Choice direct GME payments, the additional payment amount specified in paragraph (c) of this section is calculated according to the following steps:

(1) *Step one.* Each calendar year, determine for each eligible hospital the total—

(i) Medicare payments received for approved nursing or allied health education programs based on data from the settled cost reports for the period(s) ending in the fiscal year that is 2 years prior to the current calendar year; and

(ii) Inpatient days for that same cost reporting period.

(iii) Medicare+Choice inpatient days for that same cost reporting period.

(2) *Step two.* Using the data from step one, determine the ratio of the individual hospital's total nursing or allied health payments, to its total inpatient days. Multiply this ratio by the hospital's total Medicare+Choice inpatient days.

(3) *Step three.* CMS will determine, using the best available data, for all eligible hospitals the total of all—

(i) Nursing and allied health education program payments made to all hospitals for all cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year;

(ii) Inpatient days from those same cost reporting periods; and

(iii) Medicare+Choice inpatient days for those same cost reporting periods.

(4) *Step four.* Using the data from step three, CMS will determine the ratio of the total of all nursing and allied health education program payments made to all hospitals for all cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year, to the total of all inpatient days from those same cost reporting periods. CMS will multiply this ratio by the total of all Medicare+Choice inpatient days for those same cost reporting periods.

(5) *Step 5.* Calculate the ratio of the product determined in step two to the product determined in step four.

(6) *Step 6.* Multiply the ratio calculated in step five by the amount determined in accordance with paragraph (f) of this section for the current calendar year. The resulting product is each respective hospital's additional payment amount.

(f) *Calculation of the payment ''pool.''*

(1) Subject to paragraph (f)(3) of this section, each calendar year, CMS will calculate a Medicare+Choice nursing and allied health payment ''pool'' according to the following steps:

(i) Determine the ratio of projected total Medicare+Choice direct GME payments made in accordance with the

provisions of § 413.76(c) across all hospitals in the current calendar year to projected total direct GME payments made across all hospitals in the current calendar year.

(ii) Multiply the ratio calculated in paragraph (f)(1)(i) of this section by projected total Medicare nursing and allied health education reasonable cost payments made to all hospitals in the current calendar year.

(2) The resulting product of the steps under paragraphs (f)(1)(i) and (f)(1)(ii) of this section is the Medicare+Choice nursing and allied health payment ''pool'' for the current calendar year.

(3) The payment pool may not exceed $60 million in any calendar year.

[65 FR 47051, Aug. 1, 2000, as amended at 66 FR 32195, June 13, 2001; 69 FR 49265, Aug. 11, 2004; 70 FR 47489, Aug. 12, 2005]

§ 413.88 Incentive payments under plans for voluntary reduction in number of medical residents.

(a) *Statutory basis.* This section implements section 1886(h)(6) of the Act, which establishes a program under which incentive payments may be made to qualifying entities that develop and implement approved plans to voluntarily reduce the number of residents in medical residency training.

(b) *Qualifying entity defined.* ''Qualifying entity'' means:

(1) An individual hospital that is operating one or more approved medical residency training programs as defined in § 413.75(b) of this chapter; or

(2) Two or more hospitals that are operating approved medical residency training programs as defined in § 413.75(b) of this chapter and that submit a residency reduction application as a single entity.

(c) *Conditions for payments.* (1) A qualifying entity must submit an application for a voluntary residency reduction plan that meets the requirements and conditions of this section in order to receive incentive payments for reducing the number of residents in its medical residency training programs.

(2) The incentive payments will be determined as specified under paragraph (g) of this section.

(d) *Requirements for voluntary plans.* In order for a qualifying entity to receive incentive payments under a voluntary residency reduction plan, the qualifying entity must submit an application that contains the following information, documents, and agreements—

(1) A description of the operation of a plan for reducing the full-time equivalent (FTE) residents in its approved medical residency training programs, consistent with the percentage reduction requirements specified in paragraphs (g)(2) and (g)(3) of this section;

(2) An election of the period of residency training years during which the reductions will occur. The reductions must be fully implemented by not later than the fifth residency training year in which the plan is effective;

(3) FTE counts for the base number of residents, as defined in paragraph (g)(1) of this section, with a breakdown of the number of primary care residents compared to the total number of residents; and the direct and indirect FTE counts of the entity on June 30, 1997. For joint applicants, these counts must be provided individually and collectively;

(4) Data on the annual and cumulative targets for reducing the number of FTE residents and the ratios of the number of primary care residents to the total number of residents for the base year and for each year in the 5-year reduction period. For joint applicants, these data must be provided individually and collectively;

(5) An agreement to not reduce the proportion of its primary care residents to its total number of residents below the proportion that exists in the base year, as specified in paragraph (g)(1) of this section;

(6) An agreement to comply with data submission requirements deemed necessary by CMS to make annual incentive payments during the 5-year residency reduction plan, and to fully cooperate with additional audit and monitoring activities deemed necessary by CMS;

(7) For a qualifying entity that is a member of an affiliated group as defined in § 413.75(b), a statement that all members of the group agree to an aggregate FTE cap that reflects—

(i) The reduction in the qualifying entity's FTE count as specified in the plan during each year of the plan; and

(ii) The 1996 FTE count of the other hospital(s) in the affiliated group.

(8) A statement indicating voluntary participation in the plan under the terms of this section, signed by each hospital that is part of the applying entity.

(e) *Deadline for applications.* A qualifying entity must submit an application that meets the requirements of paragraph (d) of this section at least one day prior to the first day of the period to which the plan would be effective but no later than November 1, 1999. The application must be submitted to the fiscal intermediary, with a copy to CMS.

(f) *Effective dates of plans.* Residency reduction plans that are submitted to the fiscal intermediary on or after September 17, 1999 but on or before November 1, 1999, may be effective for portions of cost reporting periods beginning no earlier than the day after the date of the application.

(g) *Residency reduction requirements*—(1) *Base number of residents defined.* (i) ''Base number of residents'' means the lesser of—

(A) The number of FTE residents in all approved medical residency training programs of the qualifying entity (before application of weighting factors under § 413.79) for the most recent residency training year ending June 30, 1996; or

(B) The number of FTE residents in all approved medical residency training programs of the qualifying entity (before application of weighting factors under § 413.79) for any subsequent residency training year that ends before the date the entity submits its plan to the fiscal intermediary and CMS.

(ii) The residency training year used to determine the base number of residents is the ''base year'' for determining reduction requirements.

(iii) The qualifying entity's base number of residents may not be adjusted to reflect adjustments that may otherwise be made to the entity's FTE caps for new medical residency training programs.

(2) *Qualifying entity consisting of individual hospital.* The base number of FTE residents in all the approved medical residency training programs operated by or through a qualifying entity consisting of an individual hospital must be reduced as follows:

(i) If the base number of residents exceeds 750, residents, by at least 20 percent of the base number.

(ii) If the base number of residents exceeds 600 but is less than or equal to 750 residents—

(A) By 150 residents; or

(B) By 20 percent, if the qualifying entity increases the number of primary care residents included in the base number by at least 20 percent.

(iii) If the base number of residents is 600 or less residents—

(A) By 25 percent; or

(B) By 20 percent, if the qualifying entity increases the number of primary care residents included in the base number of residents by at least 20 percent.

(3) *Qualifying entity consisting of two or more hospitals.* The base number of FTE residents in the aggregate for all the approved medical residency training programs operated by or through a qualifying entity consisting of two or more hospitals must be reduced—

(i) By 25 percent; or

(ii) By 20 percent, if the qualifying entity increases the number of primary care residents included in the base number of residents by at least 20 percent.

(4) *Treatment of rotating residents.* A qualifying entity will not be eligible for incentive payments for a reduction in the base number of residents if the reduction is a result of the entity rotating residents to another hospital that is not a part of its voluntary residency reduction plan.

(5) *Updates to annual and cumulative targets* (i) Except as provided in paragraph (g)(5)(ii) of this section an entity with an approved voluntary residency reduction plan may not change the annual and cumulative reduction targets that are specified in its plan in accordance with paragraphs (g)(2) and (g)(3) of this section.

(ii) An entity may update annual reduction targets specified in its plan only if—

(A) It has failed to meet a specified annual target for a plan year in the 5-year period; and

(B) It wishes to adjust future annual targets for the remaining years of the

plan in order to comply with its cumulative target.

(iii) An updated plan allowed under paragraph (g)(5)(ii) of this section must be submitted prior to the beginning of each July 1 medical residency training year during the plan years.

(h) *Computation of incentive payment amount.* (1) Incentive payments to qualifying entities that meets the requirements and conditions of paragraphs (d) and (g) of this section will be computed as follows:

(i) *Step 1.* Determine the amount (if any) by which the payment amount that would have been made under § 413.76 if there had been a 5-percent reduction in the number of FTE residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds the amount of payment that would have been made under § 413.76 in each year under the voluntary residency reduction plan, taking into account the reduction in the number of FTE residents under the plan.

(ii) *Step 2.* Determine the amount (if any) by which the payment amount that would have been made under § 412.105 of this chapter if there had been a 5-percent reduction in the number of FTE residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds the payment amount made under § 412.105 of this chapter in each year under the voluntary residency reduction plan, taking into account the actual reduction in the number of FTE residents.

(iii) *Step 3.* Determine the amount (if any) by which the payment amount that would have been made under § 412.322 of this chapter if there had been a 5-percent reduction in the number of FTE residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds the payment amount made under § 412.322 of this chapter in each year under the voluntary residency reduction plan, taking into account the actual reduction in the number of FTE residents.

(iv) *Step 4.* Multiply the sum of the amounts determined under paragraph (h)(i), (ii), and (iii) of this section by the applicable hold harmless percentages specified in paragraph (i) of this section.

(2) The determination of the amounts under paragraph (h)(1) of this section for any year is based on the applicable Medicare statutory provisions in effect on the application deadline date for the voluntary reduction plan specified under paragraph (e) of this section.

(i) *Applicable hold-harmless percentage.* The applicable hold-harmless percentages for each year in which the residency reduction plan is in effect are as follows:

(1) 100 percent for the first and second residency training years;

(2) 75 percent for the third year;

(3) 50 percent for the fourth year; and

(4) 25 percent for the fifth year.

(j) *Payments to qualifying entities.* Annual incentive payments through cost reports will be made to each hospital that is or is part of a qualifying entity over the 5-year reduction period if the qualifying entity meets the annual and cumulative reduction targets specified in its voluntary reduction plan.

(k) *Penalty for noncompliance*—(1) *Nonpayment.* No incentive payment may be made to a qualifying entity for a residency training year if the qualifying entity has failed to reduce the number of FTE residents according to its voluntary residency reduction plan.

(2) *Repayment of incentive amounts.* The qualifying entity is liable for repayment of the total amount of incentive payments it has received if the qualifying entity—

(i) Fails to reduce the base number of residents by the percentages specified in paragraphs (g)(2) and (g)(3) of this section by the end of the fifth residency training year; or

(ii) Increases the number of FTE residents above the number of residents permitted under the voluntary residency reduction plan as of the completion date of the plan.

(l) *Postplan determination of FTE caps for qualifying entities*—(1) *No penalty imposed.* Upon completion of a voluntary residency reduction plan, if no penalty is imposed, the qualifying entity's 1996 FTE count is permanently adjusted to equal the unweighted FTE count used for direct GME payments for the last residency training year in which a qualifying entity participates.

(2) *Penalty imposed.* Upon completion of the voluntary residency reduction plan—

(i) *During repayment period.* If a penalty is imposed under paragraph (k)(2) of this section, during the period of repayment, the qualifying entity's FTE count is as specified in paragraph (l)(1) of this section.

(ii) *After repayment period.* Once the penalty repayment is completed, the qualifying entity's FTE reverts back to its original 1996 FTE cap.

[64 FR 44855, Aug. 18, 1999, as amended at 69 FR 49265, Aug. 11, 2004]

§ 413.89 Bad debts, charity, and courtesy allowances.

(a) *Principle.* Bad debts, charity, and courtesy allowances are deductions from revenue and are not to be included in allowable cost; however, except for anesthetists' services described under paragraph (h) of this section, bad debts attributable to the deductibles and coinsurance amounts are reimbursable under the program.

(b) *Definitions*—(1) *Bad debts.* Bad debts are amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services. ''Accounts receivable'' and ''notes receivable'' are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future.

(2) *Charity allowances.* Charity allowances are reductions in charges made by the provider of services because of the indigence or medical indigence of the patient. Cost of free care (uncompensated services) furnished under a Hill-Burton obligation are considered as charity allowances.

(3) *Courtesy allowances.* Courtesy allowances indicate a reduction in charges in the form of an allowance to physicians, clergy, members of religious orders, and others as approved by the governing body of the provider, for services received from the provider. Employee fringe benefits, such as hospitalization and personnel health programs, are not considered to be courtesy allowances.

(c) *Normal accounting treatment: Reduction in revenue.* Bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services. Such costs have already been incurred in the production of the services.

(d) *Requirements for Medicare.* Under Medicare, costs of covered services furnished beneficiaries are not to be borne by individuals not covered by the Medicare program, and conversely, costs of services provided for other than beneficiaries are not to be borne by the Medicare program. Uncollected revenue related to services furnished to beneficiaries of the program generally means the provider has not recovered the cost of services covered by that revenue. The failure of beneficiaries to pay the deductible and coinsurance amounts could result in the related costs of covered services being borne by other than Medicare beneficiaries. To assure that such covered service costs are not borne by others, the costs attributable to the deductible and coinsurance amounts that remain unpaid are added to the Medicare share of allowable costs. Bad debts arising from other sources are not allowable costs.

(e) *Criteria for allowable bad debt.* A bad debt must meet the following criteria to be allowable:

(1) The debt must be related to covered services and derived from deductible and coinsurance amounts.

(2) The provider must be able to establish that reasonable collection efforts were made.

(3) The debt was actually uncollectible when claimed as worthless.

(4) Sound business judgment established that there was no likelihood of recovery at any time in the future.

(f) *Charging of bad debts and bad debt recoveries.* The amounts uncollectible from specific beneficiaries are to be charged off as bad debts in the accounting period in which the accounts are deemed to be worthless. In some cases an amount previously written off as a bad debt and allocated to the program may be recovered in a subsequent accounting period; in such cases the income therefrom must be used to reduce the cost of beneficiary services for the period in which the collection is made.

(g) *Charity allowances.* Charity allowances have no relationship to beneficiaries of the Medicare program and are not allowable costs. These charity allowances include the costs of uncompensated services furnished under a Hill-Burton obligation. (Note: In accordance with section 106(b) of Pub. L. 97–248 (enacted September 3, 1982), this sentence is effective with respect to any costs incurred under Medicare except that it does not apply to costs which have been allowed prior to September 3, 1982, pursuant to a final court order affirmed by a United States Court of Appeals.) The cost to the provider of employee fringe-benefit programs is an allowable element of reimbursement.

(h) *Limitations on bad debts.* In determining reasonable costs for hospitals, the amount of bad debts otherwise treated as allowable costs (as defined in paragraph (e) of this section) is reduced—

(1) For cost reporting periods beginning during fiscal year 1998, by 25 percent;

(2) For cost reporting periods beginning during fiscal year 1999, by 40 percent; and

(3) For cost reporting periods beginning during fiscal year 2000, by 45 percent.

(4) For cost reporting periods beginning during a subsequent fiscal year, by 30 percent.

(i) *Exception.* Bad debts arising from services for anesthetists paid under a fee schedule are not reimbursable under the program.

[51 FR 34793, Sept. 30, 1986, as amended at 57 FR 33898, July 31, 1992; 60 FR 63189, Dec. 8, 1995; 63 FR 41005, July 31, 1998; 66 FR 32195, June 13, 2001. Redesignated at 69 FR 49254, Aug. 11, 2004]

§ 413.90 Research costs.

(a) *Principle.* Costs incurred for research purposes, over and above usual patient care, are not includable as allowable costs.

(b) *Application.* (1) There are numerous sources of financing for health-related research activities. Funds for this purpose are provided under many Federal programs and by other tax-supported agencies. Also, many foundations, voluntary health agencies, and other private organizations, as well as individuals, sponsor or contribute to the support of medical and related research. Funds available from such sources are generally ample to meet basic medical and hospital research needs. A further consideration is that quality review should be assured as a condition of governmental support for research. Provisions for such review would introduce special difficulties in the Medicare programs.

(2) If research is conducted in conjunction with, and as a part of, the care of patients, the costs of usual patient care and studies, analyses, surveys, and related activities to serve the provider's administrative and program needs are allowable costs in the determination of payment under Medicare.

[51 FR 34793, Sept. 30, 1986, as amended at 61 FR 63748, Dec. 2, 1996]

§ 413.92 Costs of surety bonds.

Costs incurred by a provider to obtain a surety bond required by part 489, subpart F of this chapter are not included as allowable costs.

[63 FR 310, Jan. 5, 1998]

§ 413.94 Value of services of nonpaid workers.

(a) *Principle.* The value of services in positions customarily held by full-time employees performed on a regular, scheduled basis by individuals as nonpaid members of organizations under arrangements between such organizations and a provider for the performance of such services without direct remuneration from the provider to such individuals is allowable as an operating expense for the determination of allowable cost subject to the limitation contained in paragraph (b) of this section. The amounts allowed are not to exceed those paid others for similar work. Such amounts must be identifiable in the records of the institutions as a legal obligation for operating expenses.

(b) *Limitations: Services of nonpaid workers.* The services must be performed on a regular, scheduled basis in positions customarily held by full-time employees and necessary to enable the provider to carry out the functions of normal patient care and operation of

the institution. The value of services of a type for which providers generally do not remunerate individuals performing such services is not allowable as a reimbursable cost under the Medicare program. For example, donated services of individuals in distributing books and magazines to patients, or in serving in a provider canteen or cafeteria or in a provider gift shop, would not be reimbursable.

(c) *Application.* The following illustrates how a provider would determine an amount to be allowed under this principle: The prevailing salary for a lay nurse working in Hospital A is $5,000 for the year. The lay nurse receives no maintenance or special perquisites. A sister working as a nurse engaged in the same activities in the same hospital receives maintenance and special perquisites which cost the hospital $2,000 and are included in the hospital's allowable operating costs. The hospital would then include in its records an additional $3,000 to bring the value of the services rendered to $5,000. The amount of $3,000 would be allowable if the provider assumes obligation for the expense under a written agreement with the sisterhood or other religious order covering payment by the provider for the services.

§413.98 Purchase discounts and allowances, and refunds of expenses.

(a) *Principle.* Discounts and allowances received on purchases of goods or services are reductions of the costs to which they relate. Similarly, refunds of previous expense payments are reductions of the related expense.

(b) *Definitions*—(1) *Discounts.* Discounts, in general, are reductions granted for the settlement of debts.

(2) *Allowances.* Allowances are deductions granted for damage, delay, shortage, imperfection, or other causes, excluding discounts and returns.

(3) *Refunds.* Refunds are amounts paid back or a credit allowed on account of an overcollection.

(c) *Normal accounting treatment—Reduction of costs.* All discounts, allowances, and refunds of expenses are reductions in the cost of goods or services purchased and are not income. If they are received in the same accounting period in which the purchases were made or expenses were incurred, they will reduce the purchases or expenses of that period. However, if they are received in a later accounting period, they will reduce the comparable purchases or expenses in the period in which they are received.

(d) *Application.* (1) Purchase discounts have been classified as cash, trade, or quantity discounts. Cash discounts are reductions granted for the settlement of debts before they are due. Trade discounts are reductions from list prices granted to a class of customers before consideration of credit terms. Quantity discounts are reductions from list prices granted because of the size of individual or aggregate purchase transactions. Whatever the classification of purchase discounts, like treatment in reducing allowable costs is required. In the past, purchase discounts were considered as financial management income. However, modern accounting theory holds that income is not derived from a purchase but rather from a sale or an exchange and that purchase discounts are reductions in the cost of whatever was purchased. The true cost of the goods or services is the net amount actually paid for them. Treating purchase discounts as income would result in an overstatement of costs to the extent of the discount.

(2) As with discounts, allowances, and rebates received from purchases of goods or services, refunds of previous expense payments are clearly reductions in costs and must be reflected in the determination of allowable costs. This treatment is equitable and is in accord with that generally followed by other governmental programs and third-party payment organizations paying on the basis of cost.

§413.100 Special treatment of certain accrued costs.

(a) *Principle.* As described in §413.24(b)(2), under the accrual basis of accounting, revenue is reported in the period in which it is earned and expenses are reported in the period in which they are incurred. In the case of accrued costs described in this section, for Medicare payment purposes the costs are allowable in the year in which the costs are accrued and claimed for Medicare payment only

under the conditions set forth in paragraph (c) of this section.

(b) *Definitions*—(1) *All-inclusive paid days off benefit.* An all-inclusive paid days off benefit replaces other vacation and sick pay plans. It is a formal plan under which, based on actual hours worked, all employees accrue vested leave or payment in lieu of vested leave for any combination of types of leave, such as illness, medical appointments, holidays, and vacations.

(2) *Self-insurance.* Self-insurance is a means by which a provider independently or as part of a group undertakes the risk of protecting itself against anticipated liabilities by providing funds in an amount equal to anticipated liabilities, rather than by purchasing insurance coverage.

(c) *Recognition of accrued costs*—(1) *General.* Although Medicare recognizes, in the year of accrual, the accrual of costs for which a provider has not actually expended funds during the current cost reporting period, for purposes of payment Medicare does not recognize the accrual of costs unless the related liabilities are liquidated timely.

(2) *Requirements for liquidation of liabilities.* For accrued costs to be recognized for Medicare payment in the year of the accrual, the requirements set forth below must be met with respect to the liquidation of related liabilities. If liquidation does not meet these requirements, the cost is disallowed, generally in the year of accrual, except as specified in paragraph (c)(2)(ii) of this section.

(i) *A short-term liability.* (A) Except as provided in paragraph (c)(2)(i)(B) of this section, a short-term liability, including the current portion of a long-term liability (for example, mortgage interest payments due to be paid in the current year), must be liquidated within 1 year after the end of the cost reporting period in which the liability is incurred.

(B) If, within the 1-year time limit, the provider furnishes to the intermediary sufficient written justification (based upon documented evidence) for nonpayment of the liability , the intermediary may grant an extension for good cause. The extension may not exceed 3 years beyond the end of the cost reporting year in which the liability was incurred.

(ii) *Vacation pay and all-inclusive paid days off.* (A) If the provider's vacation policy, or its policy for all-inclusive paid days off, is consistent for all employees, liquidation of the liability must be made within the period provided for by that policy.

(B) If the provider's vacation policy, or its policy for all-inclusive paid days off, is not consistent for all employees, liquidation of the liability must be made within 2 years after the close of the cost reporting period in which the liability is accrued.

(C) If payment is not made within the required time period or if benefits are forfeited by the employee, an adjustment to disallow the accrued cost is made in the current period (that is, the latest year in which payment should have been made or the year in which the benefits are forfeited) rather than in the period in which the cost was accrued and claimed for Medicare payment. However, an intermediary may choose to require the adjustment in the period in which the cost was accrued and claimed for Medicare payment if the cost report for that period is open or can be reopened as provided in § 405.1885 of this chapter, and if the intermediary believes the adjustment is more appropriate in that period.

(iii) *Sick pay.* (A) If sick leave is vested and funded in a deferred compensation plan, liabilities related to the contributions to the fund must be liquidated, generally within 1 year after the end of the cost reporting period in which the liability is incurred. If, within the 1-year time limit, the provider furnishes to the intermediary sufficient written justification (based upon documented evidence) for nonpayment of the liability, the intermediary may grant an extension for good cause. The extension may not exceed 3 years beyond the end of the cost reporting year in which the liability was incurred. Contributions to the deferred compensation plan must be reduced to reflect estimated forfeitures. Actual forfeitures above or below estimated forfeitures must be used to adjust annual contributions to the fund.

(B) If the sick leave plan grants employees the nonforfeitable right to demand cash payment for unused sick leave at the end of each year, sick pay is includable in allowable costs, without funding, in the cost reporting period in which it is earned.

(C) Sick pay paid on any basis other than that specified in paragraphs (c)(2)(iii) (A) or (B) of this section can be claimed for Medicare payment only on a cash basis for the year in which the benefits are paid.

(iv) *Compensation of owners.* Accrued liability related to compensation of owners other than sole proprietors and partners must be liquidated within 75 days after the close of the cost reporting period in which the liability occurs.

(v) *Nonpaid workers.* Obligations incurred under a legally-enforceable agreement to remunerate an organization of nonpaid workers must be discharged no later than the end of the provider's cost reporting period following the period in which the services were furnished.

(vi) *FICA and other payroll taxes—(A) General rule.* The provider's share of FICA and other payroll taxes that the provider becomes obligated to remit to governmental agencies is included in allowable costs only during the cost reporting period in which payment (upon which the payroll taxes are based) is actually made to the employee. For example, payroll taxes applicable to vacation benefits are not to be accrued in the period in which the vacation benefits themselves are accrued but rather are allowable only in the period in which the employee takes the vacation.

(B) *Exception.* If payment would be made to an employee during a cost reporting period but for the fact the regularly scheduled payment date is after the end of the period, costs of accrued payroll taxes related to the portion of payroll accrued through the end of the period, but paid to the employee after the beginning of the new period, are allowable costs in the year of accrual, subject to the liquidation requirements specified in paragraph (c)(2)(i) of this section.

(vii) *Deferred compensation.* (A) Reasonable provider payments made under unfunded deferred compensation plans are included in allowable costs only during the cost reporting period in which actual payment is made to the participating employee.

(B) Accrued liability related to contributions to a funded deferred compensation plan must be liquidated within 1 year after the end of the cost reporting period in which the liability is incurred. An extension, not to exceed 3 years beyond the end of the cost reporting year in which the liability was incurred, may be granted by the intermediary for good cause if the provider, within the 1-year time limit, furnishes to the intermediary sufficient written justification for non-payment of the liability.

(C) Postretirement benefit plans (including those addressed in Statement of Financial Accounting Standards No. 106 (December 1990)) are deferred compensation arrangements and thus are subject to the provisions of this section regarding deferred compensation and to applicable program instructions for determining Medicare payment for deferred compensation.

(viii) *Self-insurance.* Accrued liability related to contributions to a self-insurance program that are systematically made to a funding agency and that cover malpractice and comprehensive general liability, unemployment compensation, workers' compensation insurance losses, or employee health benefits, must be liquidated within 75 days after the close of the cost reporting period.

[60 FR 33136, June 27, 1995, as amended at 64 FR 51909, Sept. 27, 1999]

§413.102 Compensation of owners.

(a) *Principle.* A reasonable allowance of compensation for services of owners is an allowable cost provided that the services are actually performed in a necessary function.

(b) *Definitions.* (1) *Compensation.* Compensation means the total benefit received by the owner for the services he furnishes to the institution. It includes the following items:

(i) Salary amounts paid for managerial, administrative, professional, and other services.

(ii) Amounts paid by the institution for the personal benefit of the proprietor.

(iii) The cost of assets and services that the proprietor receives from the institution.

(iv) Deferred compensation.

(2) *Reasonableness.* Reasonableness requires that the compensation allowance—

(i) Be such an amount as would ordinarily be paid for comparable services by comparable institutions; and

(ii) Depend upon the facts and circumstances of each case.

(3) *Necessary.* Necessary requires that the function be—

(i) Such that had the owner not furnished the services, the institution would have had to employ another person to perform the services; and

(ii) Pertinent to the operation and sound conduct of the institution.

(c) *Application.* (1) Owners of provider organizations often furnish services as managers, administrators, or in other capacities. In such cases, it is equitable that reasonable compensation for the services furnished to be an allowable cost. To do otherwise would disadvantage such owners in comparison with corporate providers or providers employing persons to perform similar services.

(2) Ordinarily, compensation paid to proprietors is a distribution of profits. However, if a proprietor furnishes necessary services for the institution, the institution is in effect employing his services, and a reasonable compensation for these services is an allowable cost. In corporate providers, the salaries of owners who are also employees are subject to the same requirements of reasonableness. If the services are furnished on less than a full-time basis, the allowable compensation should reflect an amount proportionate to a full-time basis. Reasonableness of compensation may be determined by reference to, or in comparison with, compensation paid for comparable services and responsibilities in comparable institutions; or it may be determined by other appropriate means.

§ 413.106 Reasonable cost of physical and other therapy services furnished under arrangements.

(a) *Principle.* The reasonable cost of the services of physical, occupational, speech, and other therapists, and services of other health specialists (other than physicians), furnished under arrangements (as defined in section 1861(w) of the Act) with a provider of services, a clinic, a rehabilitation agency or a public health agency, may not exceed an amount equivalent to the prevailing salary and additional costs that would reasonably have been incurred by the provider or other organization had such services been performed by such person in an employment relationship, plus the cost of other reasonable expenses incurred by such person in furnishing services under such an arrangement. However, if the services of a therapist are required on a limited part-time basis, or to perform intermittent services, payment may be made on the basis of a reasonable rate per unit of service, even though this rate may be greater per unit of time than salary-related amounts, if the greater payment is, in the aggregate, less than the amount that would have been paid had a therapist been employed on a full-time or regular part-time salaried basis. Pursuant to section 17(a) of Public Law 93–233 (87 Stat. 967), the provisions of this section are effective for cost reporting periods beginning after March, 1975.

(b) *Definitions*—(1) *Prevailing salary.* The prevailing salary is the hourly salary rate based on the 75th percentile of salary ranges paid by providers in the geographical area, by type of therapy, to therapists working full time in an employment relationship.

(2) *Fringe benefit and expense factor.* The standard fringe benefit and expense factor is an amount that takes account of fringe benefits, such as vacation pay, insurance premiums, pension payments, allowances for job-related training, meals, etc., generally received by an employee therapist, as well as expenses, such as maintaining an office, appropriate insurance, etc., an individual not working as an employee might incur in furnishing services under arrangements.

(3) *Adjusted hourly salary equivalency amount.* The adjusted hourly salary equivalency amount is the prevailing hourly salary rate plus the standard fringe benefit and expense factor. This amount is determined on a periodic

basis for appropriate geographical areas.

(4) *Travel allowance.* A standard travel allowance is an amount that is recognized, in addition to the adjusted hourly salary equivalency amount.

(5) *Limited part-time or intermittent services.* Therapy services are considered to be on a limited part-time or intermittent basis if the provider or other organization furnishing the services under arrangements requires the services of a therapist or therapists on an average of less than 15 hours per week. This determination is made by dividing the total hours of services furnished during the cost reporting period by the number of weeks in which the services were furnished in the cost reporting period regardless of the number of days in each week in which services were performed.

(6) *Guidelines.* Guidelines are the amounts published by CMS reflecting the application of paragraphs (b) (1) through (4) of this section to an individual therapy service and a geographical area. Other statistically valid data may be used to establish guidelines for a geographical area, provided that the study designs, questionnaires and instructions, as well as the resultant survey data for determining the guidelines are submitted to and approved in advance by CMS. Such data must be arrayed so as to permit the determination of the 75th percentile of the range of salaries paid to full-time employee therapists.

(7) *Administrative responsibility.* Administrative responsibility is the performance of those duties that normally fall within the purview of a department head or other supervisor. This term does not apply to directing aides or other assistants in furnishing direct patient care.

(c) *Application.* (1) Under this provision, CMS will establish criteria for use in determining the reasonable cost of physical, occupational, speech, and other therapy services and the services of other health specialists (other than physicians) furnished by individuals under arrangements with a provider of services, a clinic, a rehabilitation agency, or public health agency. It is recognized that providers have a wide variety of arrangements with such individuals. These individuals may be independent practitioners or employees of organizations furnishing various health care specialists. This provision does not require change in the substance of these arrangements.

(2) If therapy services are performed under arrangements at a provider site on a full-time or regular part-time basis, the reasonable cost of such services may not exceed the amount determined by taking into account the total number of hours of services furnished by the therapist, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished and a standard travel allowance.

(3) If therapy services are performed under arrangements on a limited part-time or intermittent basis at the provider site, the reasonable cost of such services is evaluated on a reasonable rate per unit of service basis, except that payment for these services, in the aggregate, during the cost reporting period, may not exceed the amount that would be determined to be reasonable under paragraph (c)(2) of this section, had a therapist furnished the provider or other organization furnishing the services under arrangements 15 hours of service per week on a regular part-time basis for the weeks in which services were furnished by the non-employee therapist.

(4) If an HHA furnishes services under arrangements at the patient's residence or in other situations in which therapy services are not performed at the provider's site, the reasonable cost of such services is evaluated as follows:

(i) *Time records available.* If time records of HHA visits are maintained by the provider, the reasonable cost of such services is evaluated on a unit-of-time basis, by taking into account the total number of hours of service furnished by the therapist, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished, and a standard travel allowance for each visit. However, if the travel time of the therapist is accurately recorded by the therapist, and approved and maintained by the provider, the reasonable cost of such

services may be evaluated, at the option of the provider, by taking into account the total number of hours of service furnished by the therapist, including travel time, and the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished. This option does not apply to services furnished by HHAs under arrangements with providers other than HHAs.

(ii) *No time records available.* If time records are unavailable or found to be inaccurate, each HHA visit is considered the equivalent of one hour of service. In such cases, the reasonable cost of such services is determined by taking into account the number of visits made by the therapist under arrangements with such agency, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished, and a standard travel allowance.

(iii) *Limited part-time or intermittent services.* If under paragraph (c)(4) (i) or (ii) of this section, the provider required therapy services on an average of less than 15 hours per week, the services are considered limited part-time or intermittent services, and the reasonable cost of such services is evaluated on a reasonable rate per unit of service basis as described in paragraph (c)(3) of this section.

(5) If therapy services are performed in situations where compensation to a therapist employed by the provider is based, at least in part, on a fee-for-service or on a percentage of income (or commission), the guidelines will apply. The entire compensation will be subject to the guidelines in cases where the nature of the arrangements is most like an under ''arrangement'' situation, although technically the provider may treat the therapists as employees. The intent of this section is to prevent an employment relationship from being used to circumvent the guidelines.

(6) These provisions are applicable to individual therapy services or disciplines by means of separate guidelines by geographical area and apply to costs incurred after issuance of the guidelines but no earlier than the beginning of the provider's cost reporting period described in paragraph (a) of this section. Until a guideline is issued for a specific therapy or discipline, costs are evaluated so that such costs do not exceed what a prudent and cost-conscious buyer would pay for the given service.

(d) *Notice of guidelines to be imposed.* Prior to the beginning of a period to which a guideline will be applied, a notice will be published in the FEDERAL REGISTER establishing the guideline amounts to be applied to each geographical area by type of therapy.

(e) *Additional allowances.* (1) If a therapist supervises other therapists or has administrative responsibility for operating a provider's therapy department, a reasonable allowance may be added to the adjusted hourly salary equivalency amount by the intermediary based on its knowledge of the differential between therapy supervisors' and therapists' salaries in similar provider settings in the area.

(2) If a therapist performing services under arrangements furnishes equipment and supplies used in furnishing therapy services, the guideline amount may be supplemented by the cost of the equipment and supplies, provided the cost does not exceed the amount the provider, as a prudent and cost-conscious buyer, would have been able to include as allowable cost.

(f) *Exceptions.* The following exceptions may be granted but only upon the provider's demonstration that the conditions indicated are present:

(1) *Exception because of unique circumstances or special labor market conditions.* An exception may be granted under this section by the intermediary if a provider demonstrates that the costs for therapy services established by the guideline amounts are inappropriate to a particular provider because of some unique circumstances or special labor market conditions in the area.

(2) *Exception for services furnished by risk-basis HMO providers.* For special rules concerning services furnished to an HMO's enrollees who are Medicare beneficiaries by a provider owned or operated by a risk-basis HMO (see § 417.201(b) of this chapter) or related to

a risk-basis HMO by common ownership or control (see §417.250(c) of this chapter).

(3) *Exception for inpatient hospital services.* Effective with cost reporting periods beginning on or after October 1, 1983, the costs of therapy services furnished under arrangements to a hospital inpatient are excepted from the guidelines issued under this section if such costs are subject to the provisions of §413.40 or part 412 of this chapter. The intermediary will grant the exception without request from the provider.

(g) *Appeals.* A request by a provider for a hearing on the determination of an intermediary concerning the therapy costs determined to be allowable based on the provisions of this section, including a determination with respect to an exception under paragraph (f) of this section, is made to the intermediary only after submission of its cost report and receipt of the notice of amount of program reimbursement reflecting such determination, in accordance with the provisions of subpart R of part 405 of this chapter.

[51 FR 34793, Sept. 30, 1986, as amended at 63 FR 5139, Jan. 30, 1998]

§413.114 Payment for posthospital SNF care furnished by a swing-bed hospital.

(a) *Purpose and basis.* This section implements section 1883 of the Act, which provides for payment for posthospital SNF care furnished by rural hospitals and CAHs having a swing-bed approval.

(1) *Services furnished in cost reporting periods beginning prior to July 1, 2002.* Posthospital SNF care furnished in general routine inpatient beds in rural hospitals and CAHs is paid in accordance with the special rules in paragraph (c) of this section for determining the reasonable cost of this care. When furnished by rural and CAH swing-bed hospitals approved after March 31, 1988 with more than 49 beds (but fewer than 100), these services must also meet the additional payment requirements set forth in paragraph (d) of this section.

(2) *Services furnished in cost reporting periods beginning on and after July 1, 2002.* Posthospital SNF care furnished in general routine inpatient beds in rural hospitals (other than CAHs) is paid in accordance with the provisions of the prospective payment system for SNFs described in subpart J of this part, except that for purposes of this paragraph, the requirements of §413.343(a) must be met using the specific assessment instrument and data designated by CMS for this purpose. Posthospital SNF care furnished in general routine inpatient beds in CAHs is paid based on reasonable cost for cost reporting periods beginning on and after July 1, 2002 and before January 1, 2004, and is paid based on 101 percent of reasonable cost for cost reporting periods beginning on and after January 1, 2004, in accordance with the provisions of subparts A through G of this part (other than paragraphs (c) and (d) of this section).

(b) *Definitions.* For purposes of this section—

Availability date means with respect to a posthospital SNF care patient in a swing-bed hospital, the later of—

(i) Any date on which a bed is available for the patient in a Medicare-participating SNF located within the hospital's geographic region;

(ii) The date that a hospital learns that a bed is available in a Medicare-participating SNF; or

(iii) If the notice is prospective, the date that a bed will become available in a Medicare-participating SNF.

Geographic region means an area that includes the SNFs with which a hospital has traditionally arranged transfers and all other SNFs within the same proximity to the hospital. In the case of a hospital without existing transfer practices upon which to base a determination, the geographic region is an area that includes all the SNFs within 50 miles (as defined in §412.92(c)(1) of this chapter) of the hospital unless the hospital can demonstrate that the SNFs are inaccessible to its patients. In the event of a dispute as to whether an SNF is within a hospital's geographic region or the SNF is inaccessible to hospital patients, the CMS Regional Office makes a determination.

Swing-bed hospital means a hospital or CAH participating in Medicare that has an approval from CMS to provide posthospital SNF care as defined in §409.20 of this chapter, and meets the

requirements specified in § 482.66 or § 485.645 of this chapter, respectively.

(c) *Special rules for determining the reasonable cost of posthospital SNF care furnished in cost reporting periods beginning prior to July 1, 2002.* The reasonable cost of posthospital SNF care furnished by a swing-bed hospital is determined as follows:

(1) The reasonable cost of routine SNF services is based on the average Medicare rate per patient day for routine services provided in freestanding SNFs in the region where the swing-bed hospital is located. The rates are calculated using the regions as defined in section 1886(d)(2)(D) of the Social Security Act. The rates are based on the most recent year for which settled cost reporting period data are available, increased in a compounded manner, using the increase applicable to the SNF routine cost limits, up to and including the calendar year for which the rates are in effect. If the current Medicare swing-bed rate for routine extended care services furnished by a swing-bed hospital during a calendar year is less than the rate for the prior calendar year, payment is made based on the prior calendar year's rate.

(2) The reasonable cost of ancillary services furnished as posthospital SNF care is determined in the same manner as the reasonable cost of other ancillary services furnished by the hospital in accordance with § 413.55(a)(1).

(d) *Additional requirements*—(1) *General rule.* For services furnished in cost reporting periods beginning prior to July 1, 2002, in order for Medicare payment to be made to a swing-bed hospital with more than 49 beds (but fewer than 100), the following payment requirements must be met:

(i) If there is an available SNF bed in the geographic region, a posthospital SNF care patient must be transferred within 5 days (excluding weekends and holidays) of the availability date, unless the patient's physician certifies within the 5-day period that transfer is not medically appropriate.

(ii) The number of patient days for posthospital SNF care in a cost reporting period does not exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the hospital in the period. In those States that do not license their hospital beds, the hospitals must use the total number of hospital beds reported on their most recent Certificate of Need (CON), excluding bassinets. If during the cost reporting period, there is an increase or decrease in the number of ''licensed'' beds, the number of ''licensed'' beds for each part of the period is to be multiplied by the number of days for which that number of ''licensed'' beds was available. After totalling the results, compute 15 percent of the total available ''licensed'' bed days to determine the payment limitation.

(2) *Payment restrictions.* (i) The hospital must not seek payment for posthospital SNF care after the end of the 5 day period (excluding weekends and holidays) beginning on the availability date of a SNF bed unless the patient's physician has certified, within that 5 day period, that the transfer of the patient to the SNF was not medically appropriate.

(ii) The hospital must not seek payment for posthospital SNF care in a cost reporting period to the extent that they exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the period. In those States that do not license hospital beds, the hospital must use the average number of hospital beds reported on its most recent CON, excluding bassinets.

(3) *Payment exception.* Payment will continue to be made during the cost reporting period in which the 15 percent limit specified in paragraph (d)(1)(ii) of this section is reached for those patients who are receiving posthospital SNF care at the time the hospital reaches the limit.

[51 FR 34793, Sept. 30, 1986, as amended at 54 FR 37274, Sept. 7, 1989; 56 FR 54545, Oct. 22, 1991; 58 FR 30671, May 26, 1993; 61 FR 51616, Oct. 3, 1996; 62 FR 46037, Aug. 29, 1997; 66 FR 39600, July 31, 2001; 69 FR 49265, Aug. 11, 2004]

§ 413.118 Payment for facility services related to covered ASC surgical procedures performed in hospitals on an outpatient basis.

(a) *Basis and scope.* This section implements section 1833(a)(4) and (i)(3) of the Act and establishes the method for determining Medicare payments for

services related to covered ambulatory surgical center (ASC) procedures performed in a hospital on an outpatient basis. It does not apply to services furnished by an ASC operated by a hospital that has an agreement with CMS to be paid in accordance with §416.30 of this chapter. (For regulations governing ASCs see part 416 of this chapter.)

(b) *Definitions.* For purposes of this section—

Facility services are those items and services, as specified in §416.61 of this chapter, that are furnished by a hospital on an outpatient basis in connection with covered ASC surgical procedures, as described in §416.65 of this chapter.

Standard overhead amount means an amount equal to the prospectively determined payment rate that would be paid for the procedure if it had been furnished by an ASC in the same geographic area.

(c) *Payment principle.* The aggregate amount of payments for facility services, furnished in a hospital on an outpatient basis, that are related to covered ASC surgical procedures (covered under §416.65 of this chapter) is equal to the lesser of—

(1) The hospital's reasonable cost or customary charges, as determined in accordance with §413.13, reduced by deductibles and coinsurance; or

(2) The blended payment amount as described in paragraph (d) of this section, which is based on hospital-specific cost and charge data and rates paid to free-standing ASCs.

(d) *Blended payment amount.* (1) For cost reporting periods beginning on or after October 1, 1987 but before October 1, 1988, the blended payment amount is equal to the sum of—

(i) 75 percent of the hospital-specific amount (the lesser of the hospital's reasonable cost or customary charges, reduced by deductibles and coinsurance); and

(ii) 25 percent of the ASC payment amount (that is, 80 percent of the result obtained by subtracting the deductibles from the sum of the standard overhead amounts.)

(2) For the period of time beginning with the first day of a hospital's cost reporting period that begins on or after October 1, 1988 and ends on December 31, 1990, the blended payment amount is equal to 50 percent of the hospital-specific amount and 50 percent of the ASC payment amount.

(3) For portions of cost reporting periods beginning on or after January 1, 1991, the blended payment amount is equal to 42 percent of the hospital-specific amount and 58 percent of the ASC payment amount.

(4) For cost reporting periods beginning on or after October 1, 1988 and before January 1, 1995, the blended payment amount is equal to the sum of 75 percent of the hospital-specific amount and 25 percent of the ASC payment amount for a hospital that makes an application to its fiscal intermediary and meets the following requirements.

(i) More than 60 percent of the hospital's inpatient hospital discharges, as described in §412.60 of this chapter, occurring during its cost reporting period beginning on or after October 1, 1986 and before October 1, 1987, are classified in diagnosis related groups 36 through 74.

(ii) During its cost reporting period beginning on or after October 1, 1986 and before October 1, 1987, more than 30 percent of the hospital's total revenues is derived from outpatient services.

(5) For portions of cost reporting periods beginning on or after October 1, 1997, for purposes of calculating the blended payment amount under paragraph (d)(4) of this section, the ASC payment amount is the sum of the standard overhead amounts reduced by deductibles and coinsurance as defined in section 1866(a)(2)(ii) of the Act.

(e) *Aggregation of cost, charges, and the blended amount.* For purposes of determining the correct payment amount under paragraphs (c) and (d) of this section, all reasonable costs and customary charges attributable to facility services furnished during a cost reporting period are aggregated and treated separately from the reasonable costs and customary charges attributable to all other services furnished in the hospital.

[52 FR 36773, Oct. 1, 1987; 52 FR 37715, Oct. 8, 1987, as amended at 55 FR 33699, Aug. 17, 1990; 55 FR 34797, Aug. 24, 1990; 57 FR 36017, Aug. 12, 1992; 57 FR 45113, Sept. 30, 1992; 65 FR 18541, Apr. 7, 2000]

§ 413.122 Payment for hospital outpatient radiology services and other diagnostic procedures.

(a) *Basis and purpose.* (1) This section implements section 1833(n) of the Act and establishes the method for determining Medicare payments for radiology services and other diagnostic procedures performed by a hospital on an outpatient basis.

(2) For purposes of this section—

(i) Radiology services include diagnostic and therapeutic radiology, nuclear medicine, CAT scan procedures, magnetic resonance imaging, ultrasound and other imaging services; and

(ii) Other diagnostic procedures are those identified by CMS, and do not include diagnostic radiology procedures or diagnostic laboratory tests.

(b) *Payment for hospital outpatient radiology services.* (1) The aggregate payment for hospital outpatient radiology services furnished on or after October 1, 1988 is equal to the lesser of the following:

(i) The hospital's reasonable cost or customary charges, as determined in accordance with § 413.13, reduced by the applicable Part B annual deductible and coinsurance amounts.

(ii) The blended payment amount described in paragraph (b)(2) of this section.

(2) The blended payment amount for hospital outpatient radiology services furnished on or after October 1, 1988, but before October 1, 1989, is equal to the sum of—

(i) 65 percent of the hospital-specific amount (the hospital's reasonable cost or customary charges, whichever is less, reduced by the applicable Part B annual deductible and coinsurance amounts); and

(ii) 35 percent of a prevailing charge or fee schedule amount that is calculated as 80 percent of the amount determined by subtracting the applicable Part B annual deductible from 62 percent of the prevailing charges (or for services furnished on or after January 1, 1989, the fee schedule amount established) for the same services when furnished by participating physicians in their offices in the same locality.

(3) For hospital outpatient radiology services furnished on or after October 1, 1989, the blended payment amount is equal to the sum of 50 percent of the hospital-specific amount and 50 percent of the fee schedule amount.

(4) For hospital outpatient radiology services furnished on or after January 1, 1991, the blended payment amount is equal to the sum of 42 percent of the hospital-specific amount and 58 percent of the fee schedule amount.

(5) For hospital outpatient radiology services furnished on or after October 1, 1997, the blended payment amount is equal to the sum of—

(i) 42 percent of the hospital-specific amount; and

(ii) 58 percent of the fee schedule amount calculated as 62 percent of the sum of the fee schedule amounts payable for the same services when furnished by participating physicians in their offices in the same locality, less deductible and coinsurance as defined in section 1866(a)(2)(A)(ii) of the Act.

(c) *Payment for other diagnostic procedures.* (1) The aggregate payment for other diagnostic procedures performed by a hospital on an outpatient basis on or after October 1, 1989 is equal to the lesser of the following:

(i) The hospital's reasonable cost or customary charges, as determined in accordance with § 414.13, reduced by the applicable Part B annual deductible and coinsurance amounts.

(ii) The blended payment described in paragraph (c)(2) of this section.

(2) The blended payment amount for other diagnostic procedures furnished on or after October 1, 1989, but before October 1, 1990, is equal to the sum of—

(i) 65 percent of the hospital-specific amount (the hospital's reasonable cost or customary charges, whichever is less, reduced by the applicable Part B annual deductible and coinsurance amounts); and

(ii) 35 percent of a prevailing charge amount that is calculated as 80 percent of the amount determined by subtracting the applicable Part B annual deductible from 42 percent of the prevailing charges for the same services furnished by participating physicians in their offices in the same locality.

(3) For other diagnostic procedures performed by a hospital on or after October 1, 1990, the blended payment is

equal to 50 percent of the hospital-specific amount and 50 percent of the prevailing charge amount.

(4) For other diagnostic services furnished on or after October 1, 1997, the blended payment amount is equal to the sum of—

(i) 50 percent of the hospital-specific amount; and

(ii) 50 percent of the fee schedule amount calculated as 42 percent of the sum of the fee schedule amounts payable for the same services when furnished by participating physicians in their offices in the same locality less deductible and coinsurance as defined in section 1866(a)(2)(A)(ii) of the Act.

[56 FR 8842, Mar. 1, 1991, as amended at 57 FR 36017, Aug. 12, 1992; 65 FR 18542, Apr. 7, 2000]

§413.123 Payment for screening mammography performed by hospitals on an outpatient basis.

(a) *Basis and scope*. This section implements section 1834(c)(1)(C) of the Act and establishes the method for determining Medicare payment for screening mammographies performed by hospitals.

(b) *Payment to hospitals for outpatient services*. Payment to hospitals for screening mammography services performed on an outpatient basis is determined in accordance with the technical component billing requirements in §405.534(d) of this chapter.

[55 FR 53522, Dec. 31, 1990, as amended at 59 FR 49834, Sept. 30, 1994]

§413.124 Reduction to hospital outpatient operating costs.

(a) Except for sole community hospitals, as defined in §412.92 of this chapter, and critical access hospitals, the reasonable costs of outpatient hospital services (other than capital-related costs of these services) are reduced by 5.8 percent for services furnished during portions of cost reporting periods occurring on or after October 1, 1990 and until the first date that the prospective payment system under part 419 of this chapter is implemented.

(b) For purposes of determining the blended payment amounts of ambulatory surgical center approved surgical procedures performed in the hospital outpatient setting under §413.118 and hospital outpatient radiology services and other diagnostic procedures under §413.122, the reduction is applicable only to the hospital-specific portion of the blended payment amounts.

[57 FR 36017, Aug. 12, 1992, as amended at 59 FR 26960, May 25, 1994; 62 FR 46037, Aug. 29, 1997; 65 FR 18542, Apr. 07, 2000]

§413.125 Payment for home health agency services.

(a) For additional rules on the allowability of certain costs incurred by home health agencies, see §§409.46 and 409.49(b) of this chapter.

(b) The reasonable cost of outpatient rehabilitation services furnished by a home health agency to homebound patients who are not entitled to home health benefits may not exceed the amounts payable under the physician fee schedule for comparable services effective January 1, 1999.

[59 FR 65497, Dec. 20, 1994, as amended at 63 FR 58910, Nov. 2, 1998]

Subpart G—Capital-Related Costs

§413.130 Introduction to capital-related costs.

(a) *General rule*. Capital-related costs and an allowance for return on equity are limited to the following:

(1) Net depreciation expense as determined under §§413.134, 413.144, and 413.149, adjusted by gains and losses realized from the disposal of depreciable assets under §413.134(f).

(2) Taxes on land or depreciable assets used for patient care.

(3) Leases and rentals, including license and royalty fees, for the use of depreciable assets or land, as described in paragraph (b) of this section.

(4) The costs of betterments and improvements as described in paragraph (c) of this section.

(5) The costs of minor equipment that are capitalized, rather than expensed, as described in paragraph (d) of this section.

(6) Insurance expense on depreciable assets, as described in paragraph (e) of this section.

(7) Interest expense as determined under §413.153, subject to the qualifications of paragraph (f) of this section.

(8) For certain proprietary providers, return on equity capital, as determined under §413.157.

(9) The capital-related costs of related organizations (as described in § 413.17), as determined in accordance with paragraph (g) of this section.

(10) Debt issuance costs, debt discounts, and debt redemption costs, if the associated debt was incurred to acquire land or depreciable assets used for patient care or to refinance existing debt for which the original purpose was to acquire land or depreciable assets used for patient care.

(11) The apportionment of the capital-related costs of jointly owned assets among the owners must be on a basis that reflects the relative use by each owner, rather than the ownership share or the amount of time the asset is located at each owners site.

(b) *Leases and rentals.* (1) Subject to the qualifications of paragraphs (b) (2), (4), (5), and (8) of this section, leases and rentals, including licenses and royalty fees, are includable in capital-related costs if they relate to the use of assets that would be depreciable if the provider owned them outright or they relate to land, which is neither depreciable nor amortizable if owned outright. The terms ''*leases*'' and ''*rentals of assets*'' signify that a provider has possession, use, and enjoyment of the assets.

(2) For sale and leaseback agreements for hospitals and SNFs entered into before October 23, 1992 and for sale and leaseback agreements for other providers entered into at any time, a provider may include incurred rental charges in its capital-related costs, as specified in a sale and leaseback agreement with a nonrelated purchaser (including shared service organizations not related within the meaning of § 413.17) involving plant facilities or equipment only if the following conditions are met:

(i) The rental charges are reasonable based on the following—

(A) Consideration of rental charges of comparable facilities and market conditions in the area;

(B) The type, expected life, condition, and value of the facilities or equipment rented; and

(C) Other provisions of the rental agreements.

(ii) Adequate alternative facilities or equipment that would serve the purpose are not or were not available at lower cost.

(iii) The leasing was based on economic and technical considerations.

(3) If the conditions of paragraph (b)(2) of this section are not met, the amount a provider may include in its capital-related costs as rental or lease expense under a sale and leaseback agreement may not exceed the amount that the provider would have included in its capital-related costs had the provider retained legal title to the facilities or equipment, such as interest on mortgage, taxes, depreciation, and insurance costs.

(4) For sale and leaseback agreements for hospitals and SNFs entered into on or after October 23, 1992, the amount a provider may include in its capital-related costs as rental or lease expense may not exceed the amount that the provider would have included in its capital-related costs had the provider retained legal title to the facilities or equipment, such as interest expense on mortgages, taxes, depreciation, and insurance costs (the costs of ownership). This limitation applies both on an annual basis and over the useful life of the asset.

(i) If in the early years of the lease, the annual rental or lease costs are less than the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are more than the annual costs of ownership, in the years that the annual rental or lease costs are more than the annual costs of ownership, the provider may include in capital-related costs annually the actual amount of rental or lease costs. The aggregate rental or lease costs included in capital-related costs may not exceed the aggregate costs of ownership that would have been included in capital-related costs over the useful life of the asset had the provider retained legal title to the asset.

(ii) If in the early years of the lease, the annual rental or lease costs exceed the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are less than the annual costs of ownership, the provider may carry forward amounts of rental or lease costs that were not included in capital-related costs in the early years

of the lease due to the costs of ownership limitation, and include these amounts in capital-related costs in the years of the lease when the annual rental or lease costs are less than the annual costs of ownership.

(iii) In any given year the amount of actual annual rental or lease costs plus the amount carried forward to that year may not exceed the amount of the costs of ownership for that year.

(iv) In the aggregate, the amount of rental or lease costs included in capital-related costs may not exceed the amount of the costs of ownership that the provider could have included in capital-related costs had the provider retained legal title to the asset.

(5) For lease purchase transactions entered into before October 23, 1992, a lease that meets the following conditions establishes a virtual purchase:

(i) The rental charge exceeds rental charges of comparable facilities or equipment in the area.

(ii) The term of the lease is less than the useful life of the facilities or equipment.

(iii) The provider has the option to renew the lease at a significantly reduced rental, or the provider has the right to purchase the facilities or equipment at a price that appears to be significantly less than what the fair market value of the facilities or equipment would be at the time acquisition by the provider is permitted.

(6)(i) If a lease is a virtual purchase under paragraph (b)(5) of this section, the rental charge is includable in capital-related costs only to the extent that it does not exceed the amount that the provider would have included in capital-related costs if it had legal title to the asset (the cost of ownership), such as straight-line depreciation, insurance, and interest. A provider may not include in its capital-related costs accelerated depreciation in this situation.

(ii) The difference between the amount of rent paid and the amount of rent allowed as capital-related costs is considered a deferred charge and is capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner, instead of being purchased, the deferred charge may be included in capital-related costs in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be included in capital-related costs to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be included in the capital-related costs to the extent of increasing the reduced rental to a fair rental value.

(7) Amounts included in lease or rental payments for repair or maintenance agreements are excluded from capital-related costs. If no amount is identified in the lease or rental agreement for maintenance, the entire lease payment is considered a capital-related cost subject to the provisions of paragraph (b)(1) of this section.

(8) For lease purchase transactions entered into on or after October 23, 1992, a lease that meets any one of the following conditions establishes a virtual purchase:

(i) The lease transfers title of the facilities or equipment to the lessee during the lease term.

(ii) The lease contains a bargain purchase option.

(iii) The lease term is at least 75 percent of the useful life of the facilities or equipment. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment.

(iv) The present value of the minimum lease payments (payments to be made during the lease term including bargain purchase option, guaranteed residual value, and penalties for failure to renew) equals at least 90 percent of the fair market value of the leased property. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment. Present value is computed using the lessee's incremental borrowing rate, unless the interest rate implicit in the lease is known and is

less than the lessee's incremental borrowing rate, in which case the interest rate implicit in the lease is used.

(9)(i) If a lease establishes a virtual purchase under paragraph (b)(8) of this section, the rental charge is includable in capital-related costs to the extent that it does not exceed the amount that the provider would have included in capital-related costs if it had legal title to the asset (the cost of ownership). The cost of ownership includes straight-line depreciation, insurance, and interest. For purposes of computing the limitation on allowable rental cost in this paragraph, a provider may not include accelerated depreciation.

(ii) The difference between the amount of rent paid and the amount of rent allowed as capital-related costs is considered a deferred charge and is capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner instead of being purchased, the deferred charge may be included in capital-related costs in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be included in capital-related costs to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be included in capital-related costs to the extent of increasing the reduced rental to a fair rental value.

(vi) If the lessee becomes the owner of the leased asset (either by operation of the lease or by other means), the amount considered as depreciation, for the purpose of having computed the limitation on rental charges in paragraph (b)(9)(i) of this section, must be used in calculating the limitation on adjustments for the purpose of determining any gain or loss under § 413.134(f) upon disposal of an asset.

(c) *Betterments and improvements.* (1) Betterments and improvements are changes which extend the estimated useful life of an asset at least two years beyond its original estimated useful life, or increase the productivity of an asset significantly over its original productivity.

(2) A provider must capitalize and prorate the costs of betterments and improvements over the remaining estimated useful life of the asset, as modified by the betterment or improvement.

(d) *Minor equipment.* A provider must include in its capital-related costs the costs of minor equipment that are capitalized rather than charged off to expense if—

(1) The net book value of minor equipment at the time the provider enters the program is prorated over three years (that is, one-third of the net book value is written off each year), and new purchases are also prorated over a 3-year period; or

(2) The cost of minor equipment is prorated over their actual useful lives.

(e) *Insurance.* (1) A provider must include in its capital-related costs the costs of insurance on depreciable assets used for patient care or insurance that provides for the payment of capital-related costs during business interruption.

(2) If an insurance policy also provides protection for other than the replacement of depreciable assets or to pay capital-related costs in the case of business interruption insurance, only that portion of the premium related to the replacement of depreciable assets or to pay capital-related costs in the case of business interruption insurance is includable in capital-related costs.

(f) *Debt premiums and debt discounts.* Debt premiums or debt discount are applied as adjustments to capital-related costs if the associated debt is incurred for acquiring land or depreciable assets used for patient care or for refinancing existing debt for which the original purpose was to acquire land or depreciable assets used for patient care.

(g) *Interest expense.* (1) A provider must include in its capital-related costs interest expense, as described in § 413.153, if such expense is incurred in—

(i) Acquiring land or depreciable assets (either through purchase or lease) used for patient care; or

(ii) Refinancing existing debt, if the original purpose of the refinanced debt was to acquire land or depreciable assets used for patient care.

(2) If investment income offset is required under §413.153(b)(2)(iii), only that portion of investment income that bears the same relationship to total investment income, as the portion of capital-related interest expense bears to total interest expense, is offset against capital-related costs.

(h) *Costs of supplying organizations*—(1) *Supplying organizations related to the provider*. (i) If the supplying organization is related to the provider within the meaning of §413.17, except as provided in paragraph (g)(1)(ii) of this section, a provider's capital-related costs include the capital-related costs of the supplying organization.

(ii) If the costs of the services, facilities or supplies being furnished exceed the open market price, or if the provisions of §413.17(d) apply, no part of the cost to the provider of the services, facilities, or supplies are considered capital-related costs, unless the services, facilities, or supplies would otherwise be considered capital-related.

(2) *Supplying organizations not related to the provider*. If the supplying organization is not related to the provider within the meaning of §413.17, no part of the charge to the provider may be considered a capital-related cost (unless the services, facilities, or supplies are capital-related in nature) unless—

(i) The capital-related equipment is leased or rented (as described in paragraph (b) of this section) by the provider;

(ii) The capital-related equipment is located on the provider's premises, or is located offsite and is on real estate owned, leased or rented by the provider; and

(iii) The capital-related portion of the charge is separately specified in the charge to the provider.

(i) *Costs excluded from capital-related costs*. The following costs are not capital-related costs. To the extent that they are allowable, they must be included in determining each provider's operating costs:

(1) Costs incurred for the repair or maintenance of equipment or facilities.

(2) Amounts included in rentals or lease payments for repair or maintenance agreements.

(3) Interest expense incurred to borrow working capital (for operating expenses).

(4) General liability insurance or any other form of insurance to provide protection other than for the replacement of depreciable assets or to pay capital-related costs in the case of business interruption.

(5) Taxes other than those assessed on the basis of some valuation of land or depreciable assets used for patient care. (Taxes not related to patient care, such as income taxes, are not allowable, and are therefore not included among either capital-related or operating costs.)

(6) The costs of minor equipment that are charged off to expense rather than capitalized as described in paragraph (d) of this section.

(7) The costs incurred for maintenance and repair insurance agreements (commonly referred to as maintenance agreements).

(j) *Reduction to capital-related costs*. (1) Except for sole community hospitals and critical access hospitals, the amount of capital-related costs of all hospital outpatient services is reduced by—

(i) 15 percent for portions of cost reporting periods occurring on or after October 1, 1989, through September 30, 1991; and

(ii) 10 percent for portions of cost reporting periods occurring on or after October 1, 1991 and until the first date that the prospective payment system under part 419 of this chapter is implemented.

(2) For purposes of determining the blended payment amounts for hospital outpatient services under §413.118 and §413.122, the reduction is applicable only to the hospital-specific portion of the blended amounts.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 56 FR 43456, Aug. 30, 1991; 57 FR 3017, Jan. 27, 1992; 57 FR 36017, Aug. 12, 1992; 57 FR 43917, Sept. 23, 1992; 58 FR 17528, Apr. 5, 1993; 59 FR 26960, May 25, 1994; 62 FR 46037, Aug. 29, 1997; 65 FR 18542, Apr. 7, 2000]

§ 413.134 Depreciation: Allowance for depreciation based on asset costs.

(a) *Principle.* An appropriate allowance for depreciation on buildings and equipment used in the provision of patient care is an allowable cost. The depreciation must be—

(1) Identifiable and recorded in the provider's accounting records;

(2) Based on the historical cost of the asset, except as specified in paragraph (j) of this section regarding donated assets; and

(3) Prorated over the estimated useful life of the asset using—

(i) The straight-line method; or

(ii) Accelerated depreciation under a declining balance method (not to exceed double the straight-line rate) or the sum-of-the-years' digits method in the following situations:

(A) Depreciable assets for which accelerated depreciation was used for Medicare purposes before August 1, 1970, including those assets for which a timely request to change from straight-line depreciation to accelerated depreciation was received by an intermediary before August 1, 1970;

(B) Depreciable assets acquired before August 1, 1970, if no election to use straight-line or accelerated depreciation was in effect on August 1, 1970, and the provider was participating in the program on August 1, 1970;

(C) Depreciable assets of a provider if construction of such depreciable asset began before February 5, 1970, and the provider was participating in the program on February 5, 1970; or

(D) Depreciable assets of a provider if a valid written contract was entered into by a provider participating in the program before February 5, 1970, for construction, acquisition, or for the permanent financing thereof, and such contract was binding on a provider on February 5, 1970, and at all times thereafter; or

(iii) A declining balance method, not to exceed 150 percent of the straight-line rate, for a depreciable asset acquired after July 31, 1970; however, this declining balance method may be used only if the cash flow from depreciation on the total assets of the institution during the reporting period, including straight-line depreciation on the assets in question, is insufficient (assuming funding of available capital not required currently for amortization and assuming reasonable interest income on such funds) to supply the funds required to meet the reasonable principal amortization schedules on the capital debts related to the provider's total depreciable assets. For each depreciable asset for which a provider requests authorization to use a declining balance method for Medicare reimbursement purposes, but not to exceed 150 percent of the straight-line rate, the provider must demonstrate to the intermediary's satisfaction that the required cash flow need exists. For each depreciable asset in which a provider justifies the use of accelerated depreciation, the intermediary must give written approval for the use of a depreciation method other than straight-line before basing any interim payment on this accelerated depreciation or making its reasonable cost determination which includes an allowance for such depreciation.

(b) *General rules*—(1) *Historical cost.* Historical cost is the cost incurred by the present owner in acquiring the asset.

(i) *All providers*—(A) *Depreciable assets acquired after July 31, 1970 and before December 1, 1997.* For depreciable assets acquired after July 31, 1970 and before December 1, 1997, and for a hospital or an SNF, acquired before July 18, 1984, the historical cost may not exceed the lower of current reproduction cost adjusted for straight-line depreciation over the life of the asset to the time of the purchase or the fair market value of the asset at the time of its purchase.

(B) *Depreciable assets acquired on or after December 1, 1997.* For depreciable assets acquired on or after December 1, 1997, the historical cost of the asset that will be recognized under this program must not exceed the historical cost less depreciation allowed to the owner of record as of August 5, 1997 (or if an asset did not exist as of August 5, 1997, the first owner of record after August 5, 1997). For this paragraph (b)(1)(i)(B), the following apply:

(*1*) An asset that was not in existence as of August 5, 1997 includes an asset that physically existed but was not owned by a provider participating in the Medicare program as of that date.

(*2*) The acquisition cost to the owner of record is subject to the limitation on historical costs described in paragraphs (g) (1), (2), and (3) of this section, and is reduced by any depreciation taken by the owner of record. The limitation on historical cost is also applied to the purchase of land, which is a capital asset that is neither depreciable nor amortizable under any circumstances. (See §§413.153(d) and 413.157(b) for application of the limitation to the cost of land for purposes of determining the allowable interest expense.)

(*3*) Acquisition cost to the owner of record includes the costs of betterment or improvements that extend the estimated useful life of an asset at least 2 years beyond its original estimated useful life or that increase the productivity of an asset significantly over its original productivity.

(*4*) For assets acquired prior to a provider's entrance into the Medicare program, the acquisition cost to the owner of record is the historical cost when acquired, rather than when the provider entered the program.

(*5*) For assets subject to the optional depreciation allowance as described in §413.139, the acquisition cost to the owner of record is the historical cost established for those assets when the provider changed to actual depreciation as described in §413.139(e). If the provider did not change to actual depreciation, as described in §413.139(e), for optional allowance assets, the acquisition cost to the owner of record is based on the provider's recorded historical cost of the asset when acquired. If the provider has no historical cost records for optional allowance assets, the acquisition cost to the owner of record is established by appraisal.

(*6*) The historical cost of an asset acquired on or after July 18, 1984 may not include costs attributable to the negotiation or settlement of the sale or purchase (by acquisition, merger, or consolidation) of any capital asset for which any payment was previously made under the Medicare program. The costs to be excluded include, but are not limited to, appraisal costs (except those incurred at the request of the intermediary under paragraph (f)(2)(iv) of this section), legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies.

(ii) *Hospitals and SNFs only*. (A) For assets acquired on or after July 18, 1984 and before December 1, 1997 and not subject to an enforceable agreement entered into before July 18, 1984, historical cost may not exceed the lowest of the following:

(*1*) The allowable acquisition cost of the asset to the owner of record as of July 18, 1984 (or, in the case of an asset not in existence as of July 18, 1984, the first owner of record of the asset after that date);

(*2*) The acquisition cost of the asset to the new owner; or

(*3*) The fair market value of the asset on the date of acquisition.

(B) For purposes of applying paragraph (b)(1)(ii)(A) of this section, an asset not in existence as of July 18, 1984 includes any asset that physically existed, but was not owned by a hospital or SNF participating in the Medicare program as of July 18, 1984.

(C) The acquisition cost to the owner of record is subject to any limitation on historical costs described in paragraphs (b)(1)(i) or (g)(1) and (2) of this section, and is not reduced by any depreciation taken by the owner of record. This limitation on historical cost is also applied to the purchase of land, a capital asset that is neither depreciable nor amortizable under any circumstances. (See §§413.153(d) and 413.157(b) for application of the limitation to the cost of land for purposes of determining allowable interest expense and return on equity capital or proprietary providers.)

(D) Acquisition cost to the owner of record includes the costs of betterments or improvements that extend the estimated useful life of an asset at least two years beyond its original estimated useful life or increase the productivity of an asset significantly over its original productivity.

(E) For assets acquired prior to a hospital's or SNF's entrance into the Medicare program, the acquisition cost to the owner of record is the historical cost of the asset when acquired, rather than when the hospital or SNF entered the program.

(F) For assets subject to the optional depreciation allowance as described in

§ 413.139, the acquisition cost to the owner of record is the historical cost established for those assets when the hospital or SNF changed to actual depreciation as described in § 413.139(e). If the hospital or SNF did not change to actual depreciation, as described in § 413.139(e), for optional allowance assets, the acquisition cost to the owner of record is established by reference to the hospital's or SNF's recorded historical cost of the asset when acquired. If the hospital or SNF has no historical cost records for optional allowance assets, the acquisition cost to the owner of record is established by appraisal.

(G) The historical cost of an asset acquired on or after July 18, 1984 may not include costs attributable to the negotiation or settlement of the sale or purchase (by acquisition, merger, or consolidation) of any capital asset for which any payment was previously made under the Medicare program. The costs to be excluded include, but are not limited to, appraisal costs (except those incurred at the request of the intermediary under paragraph (f)(2)(iv) of this section), legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies.

(iii) *Hospital-based providers other than SNFs and SNF-based providers.* For changes of ownership that involve assets of a hospital-based provider other than a SNF, or assets of a SNF-based provider, the provisions of paragraph (b)(1)(ii) of this section are not applicable. A reasonable allocation of the purchase price must be made, so that the hospital-based provider other than a SNF, or a SNF-based provider, is not affected by the limitations described in paragraph (b)(1)(ii) of this section. The historical cost of assets of providers other than hospitals and SNFs is governed by paragraph (b)(1)(i) of this section.

(2) *Fair market value.* Fair market value is the price that the asset would bring by bona fide bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price is the price that bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition.

(3) *The straight-line method.* Under the straight-line method of depreciation, the cost or other basis (for example, fair market value in the case of donated assets) of the asset, less its estimated salvage value, if any, is determined first. Then this amount is distributed in equal amounts over the period of the estimated useful life of the asset.

(4) *Declining balance method.* Under the declining balance method, the annual depreciation allowance is computed by multiplying the undepreciated cost of the asset each year by a uniform rate up to double the straight-line rate or 150 percent, as the case may be (see paragraph (a)(3) of this section for limitations on use of accelerated methods of depreciation).

(5) *Sum-of-the-years' digits method.* Under the sum-of-the-years' digits method, the annual depreciation allowance is computed by multiplying the depreciable cost basis (cost less salvage value) by a constantly decreasing fraction. The numerator of the fraction is represented by the remaining years of useful life of the asset at the beginning of each year, and the denominator is always represented by the sum of the years' digits of useful life at the time of acquisition.

(6) *Current reproduction cost.* Current reproduction cost is the cost at current prices, in a particular locality or market area, of reproducing an item of property or a group of assets. Where depreciable assets are concerned, this means the reasonable cost to have built, reproduce in kind, or, in the case of equipment or similar assets, to purchase in the competitive market.

(7) *Useful life.* The estimated useful life of a depreciable asset is its normal operating or service life to the provider, subject to the provisions in paragraph (b)(7)(i) of this section. Factors to be considered in determining useful life include normal wear and tear; obsolescence due to normal economic and technological changes; climatic and other local conditions; and the provider's policy for repairs and replacement.

(i) *Initial selection of useful life.* In selecting a proper useful life for computing depreciation under the Medicare program, providers must use the useful

life guidelines published by CMS. If CMS has not published applicable useful life guidelines, providers must use—

(A) The edition of the American Hospital Association useful life guidelines, as specified in CMS Medicare program manuals; or

(B) A different useful life specifically requested by the provider and approved by the intermediary. A different useful life may be approved by the intermediary if the provider's request is properly supported by acceptable factors that affect the determination of useful life. However, such factors as an expected early sale, retirement, demolition or abandonment of an asset, or termination of the provider from the Medicare program may not be used.

(ii) *Application of guidelines.* The provisions concerning the selection of useful life guidelines described in paragraph (b)(7)(i) of this section apply to assets acquired on or after January 1, 1981. For assets acquired before January 1, 1981, providers must use the useful life guidelines published by the American Hospital Association in its 1973 edition of *Chart of Accounts for Hospitals*, or those published by the Internal Revenue Service, or those approved for use by intermediaries as provided in paragraph (b)(7)(i)(B) of this section.

(iii) *Changing useful life.* A change in the estimated useful life may be made if clear and convincing evidence justifies a redetermination of the useful life used by the provider. Such a change must be approved by the intermediary in writing, and the factors cited in paragraphs (b)(7) and (b)(7)(i) of this section are applicable in making such redeterminations of useful life. If the request is approved, the change is effective with the reporting period immediately following the period in which the provider's request is submitted for approval.

(8) *Donated asset.* An asset is considered donated when the provider acquires the asset without making payment in the form of cash, new debt, assumed debt, property or services. Except as provided in paragraph (j)(3) of this section, if a provider makes payment in any form to acquire an asset, the payment is considered the purchase price for the purpose of determining allowable historical cost.

(9) *Net book value.* The net book value of an asset is the depreciable basis used for the Medicare program by the asset's last participating owner less depreciation recognized under the Medicare program.

(c) *Recording of depreciation.* Appropriate recording of depreciation includes the identification of the depreciable assets in use, the assets' historical costs, the assets' dates of acquisition, the method of depreciation, estimated useful lives, and the assets' accumulated depreciation.

(d) *Depreciation methods*—(1) *General.* Proration of the cost of an asset over its useful life is allowed on the straight-line method, or, when permitted under paragraph (a)(3) of this section, the declining balance or the sum-of-the-years' digits methods. One method may be used on a single asset or group of assets and another method on others. In applying the declining balance or sum-of-the-years' digits method to an asset that is not new, the undepreciated cost of the asset is treated as the cost of a new asset in computing depreciation.

(2) *Change in method.* Prior to August 1, 1970, a provider may change from the straight-line method to an accelerated method or vice versa, upon advance approval from the intermediary on a prospective basis with the request being made before the end of the first month of the prospective reporting period. Only one such change with respect to a particular asset may be made by a provider. Effective with August 1, 1970, a provider may only change from an accelerated method or optional method (see §413.139) to the straight-line method. Such a change may be made without intermediary approval and the basis for depreciation is the undepreciated cost reduced by the salvage value. Thereafter, once straight-line depreciation is selected for a particular asset, an accelerated method may not be established for that asset.

(3) *Recovery of accelerated depreciation*—(i) *General.* If a provider who has used an accelerated method of depreciation for any of its assets terminates participation in the program, or if the Medicare proportion of its allowable

costs decreases so that cumulatively substantially more depreciation was paid than would have been paid using the straight-line method of depreciation, the excess of reimbursable cost determined by using accelerated depreciation methods and paid under the program over the reimbursable cost that would have been determined and paid under the program by using the straight-line method of depreciation, will be recovered as an offset to current reimbursement due or, if the provider has terminated participation in the program, as an overpayment. In this determination of excess payment, recognition will be given to the effects the adjustment to straight-line depreciation would have on the return on equity capital and on the allowance in lieu of specific recognition of other costs in the respective years.

(ii) *Transaction between related organizations*—(A) *General.* If the termination of the provider agreement is due to a change in provider ownership, as defined in § 489.18 of this chapter, resulting from a transaction between related organizations, as defined in § 413.17, and the criteria in paragraph (b) of this section are met, the excess of reimbursable cost, as determined in paragraph (d)(3)(i) of this section may not be recovered if there is a continuation of participation by the facility in the Medicare program.

(B) *Criteria.* The following criteria must be met if the recovery of excess reimbursable cost is not to be made:

(*1*) The termination of the provider agreement is due to a change in ownership of the provider resulting from a transaction between related organizations.

(*2*) The successor provider continues to participate in the Medicare program.

(*3*) Control and the extent of the financial interest of the owners of the provider before and after the termination remain the same; that is, the successor owners acquire the same percentage of control or financial investment as the transferors had.

(*4*) All assets and liabilities of the terminated provider are transferred to the related successor participating provider.

(C) *Effect of transaction.* In transactions meeting the criteria specified in paragraph (d)(3)(ii)(B) of this section, the provision concerning recovery of excess reimbursable cost (§ 413.134(d)(3)(i)) is not applied, and the transaction is treated as follows:

(*1*) The successor provider must record the historical cost and accumulated depreciation and the method of depreciation recognized under the Medicare program, and these are considered as incurred by the successor provider for Medicare purposes.

(*2*) The Medicare program's utilization of the terminated provider is considered as having been incurred by the successor provider for Medicare purposes.

(*3*) The equity capital of the terminated provider as of the closing of its final cost reporting period must be wholly contained in the equity capital of the successor provider as of the beginning of its first cost reporting period.

(e) *Funding of depreciation.* Although funding of depreciation is not required, it is strongly recommended that providers use this mechanism as a means of conserving funds for replacement of depreciable assets. Funded depreciation account funds must be placed in readily marketable investments of the type that assures the availability and conservation of the funds. Additions to the funded depreciation account must remain in the account for at least 6 months to be considered valid funding transactions.

(1) *Incentive.* As an incentive for funding, investment income on funded depreciation is not treated as a reduction of allowable interest expense provided such investment income is deposited in, and becomes part of, the funded depreciation account at the time of receipt by the provider. Investment income earned on deposits before the 6-month period elapses are not offset unless the deposits are withdrawn for an improper purpose during this period. If a provider transfers assets of the funded depreciation account to a related organization (for example, pooling of several chain organization providers' funded depreciation accounts at the chain home office for investment purposes),

these assets shall be treated as the provider's funds and are subject to all the requirements specified in paragraph (e) of this section.

(2) *Availability of funded depreciation.* (i) CMS considers funded depreciation available for use in the acquisition or replacement of depreciable assets related to patient care unless the funded depreciation funds have been committed by contract for the acquisition of depreciable assets related to the furnishing of patient care or for other capital purposes related to patient care.

(ii) Borrowing for a purpose for which funded depreciation account funds should have been used makes the borrowing unnecessary to the extent that funded depreciation account funds were available at the time of the borrowing. Available funds in the funded depreciation account, to the extent of the unnecessary borrowing, are called ''tainted'' funds. Interest expense incurred on borrowing for a capital purpose is not an allowable cost to the extent that funded depreciation account funds were available at the time of the borrowing.

(iii) A provider can remove the ''unnecessary'' characterization of borrowing, and thereby cure tainted funded depreciation, by using the tainted funds for a proper purpose described in paragraph (e)(3)(i) of this section. However, any funded depreciation that existed at the time of the unnecessary borrowing and is not classified as tainted must be used before any of the tainted funds.

(iv) When only a portion of the borrowing is considered unnecessary under paragraph (e)(2)(ii) of this section, subsequent repayments of such borrowing from general funds are applied first to the allowable portion of the borrowing and then, when all of the allowable borrowing is repaid, to the unallowable portion of the borrowing. When funds from the funded depreciation account are used for the repayment of the unnecessary borrowing, an equivalent amount of tainted funds is cured without regard to the provisions of paragraphs (e)(2)(ii) and (e)(3)(i)(C) of this section. Similarly, where general funds are used to pay for the unallowable borrowing after the necessary borrowing has been repaid, an equivalent amount of tainted funded depreciation is cured without regard to the provisions of paragraphs (e)(2)(ii) and (e)(3)(i)(C) of this section.

(3) *Withdrawals of funded depreciation*—(i) *Proper withdrawals.* (A) Withdrawals from funded depreciation are considered proper if made either for the acquisition or replacement of depreciable assets related to the furnishing of patient care or for other capital purposes related to patient care.

(B) *First-in, first-out basis.* Proper withdrawals from funded depreciation are made on a first-in, first-out basis.

(C) *Exception.* If CMS determines that a borrowing is unnecessary because of the existence of available funded depreciation, and additional deposits have been made to funded depreciation after the occurrence of the unnecessary borrowing, withdrawals made after the date of the additional deposits are deemed to be made on a last-in, first-out basis.

(ii) *Improper withdrawals.* (A) Withdrawals from funded depreciation that do not meet the requirements for proper withdrawals under the provisions in paragraph (e)(3)(i)(A) of this section are considered improper withdrawals.

(B) Improper withdrawals from funded depreciation are made on a last-in, first-out basis. If improper withdrawals are made, interest expense is reduced in accordance with section §413.153(c)(3).

(C) Improper withdrawals will result in the offset of otherwise allowable interest expense under the offset provisions in §413.153(c)(3).

(4) *Loans from funded depreciation.* (i) When the general fund of the provider borrows from the funded depreciation to obtain working capital for normal operating expenses to furnish patient care, interest incurred by the general fund is an allowable operating cost only if the interest expense is supported by documents that evidence that the funds were borrowed and that payment of interest and repayment of the funds are required, is separately identified in the provider's accounting records, and meets the necessary and proper tests described in §§413.153(b)(2) and (b)(3). However, if the general fund

of the provider borrows from the funded depreciation account to acquire depreciable assets used in furnishing patient care, or for other capital purposes related to patient care, interest expense paid by the general fund to the funded depreciation account is not an allowable cost. Providers are expected to use the funded depreciation for these purposes.

(ii) Loans from funded depreciation to the general fund are considered investments of funded depreciation, but do not have to meet the readily marketable test described in paragraph (e) of this section. Loans made from funded depreciation are subject to the requirement that funded depreciation must be available for the acquisition of depreciable assets used to furnish patient care, or for other capital purposes related to patient care. Costs incurred to secure lines of credit from lending institutions to ensure such availability are not allowable costs.

(iii) Funding of depreciation from general funds will not be recognized to the extent of any outstanding loans from the funded depreciation account to the general fund. Deposits from the general fund into the funded depreciation account must be first applied to reduce any loans outstanding from the funded depreciation to the general fund. When the loans are repaid in full, general funds deposited in the funded depreciation account are considered as repayments of the general fund. Therefore, any subsequent interest expense of the general fund paid to the funded depreciation fund is not an allowable cost.

(iv) A provider may loan its funded depreciation to a related organization for any purpose subject to the following conditions:

(A) Authorization for such a loan by the provider's appropriate managing body of the provider, such as Board of Trustees or Board of Directors, must be on file.

(B) The funded depreciation loaned must remain available, as specified in paragraph (e)(2) of this section, to the provider making the loan. Costs incurred for lines of credit to assure such availability are not allowable costs. During the period of time that the loan is outstanding, if the provider making the loan resorts to outside borrowing for a purpose for which its funded depreciation should have been used, interest expense on an amount of the outside borrowing up to the amount of the funded depreciation that should have been available would be disallowed as unnecessary.

(C) Such loans shall be considered investments of the provider's funded depreciation, but the requirement that funded depreciation be invested in readily marketable investments as required in paragraph (e) of this section is waived for such loans.

(D) The funded depreciation account must earn interest on such loans at a rate that does not exceed the rate that would be charged for a comparable loan from an independent lending institution. This investment income will not be used to reduce the provider's interest expense if all the other conditions in paragraph (e) of this section are met. If the entity borrowing the funds is another provider participating in the Medicare program, the interest expense incurred on such loans would be allowable if the loan meets all of the interest expense requirements specified in § 413.153. (For purposes of § 413.153(b)(3)(ii), such loans are not considered to be with a related lender.)

(f) *Gains and losses on disposal of assets*—(1) *General.* Depreciable assets may be disposed of through sale, scrapping, trade-in, exchange, demolition, abandonment, condemnation, fire, theft, or other casualty. If disposal of a depreciable asset, including the sale or scrapping of an asset before December 1, 1997, results in a gain or loss, an adjustment is necessary in the provider's allowable cost. (No gain or loss is recognized on either the sale or the scrapping of an asset that occurs on or after December 1, 1997.) The amount of a gain included in the determination of allowable cost is limited to the amount of depreciation previously included in Medicare allowable costs. The amount of a loss to be included is limited to the undepreciated basis of the asset permitted under the program. The treatment of the gain or loss depends upon the manner of disposition of the asset, as specified in paragraphs (f)(2) through (6) of this section. The gain or loss on the disposition of depreciable assets

has no retroactive effect on a proprietary provider's equity capital for years prior to the year of disposition.

(2) *Bona fide sale or scrapping before December 1, 1997.* For the bona fide sale or scrapping of depreciable assets before December 1, 1997, the following apply:

(i) Except as specified in paragraph (f)(3) of this section, gains and losses realized from the bona fide sale or scrapping of depreciable assets are included in the determination of allowable cost only if the sale or scrapping occurs while the provider is participating in Medicare. The extent to which such gains and losses are included is calculated by prorating the basis for depreciation of the asset in accordance with the proportion of the asset's useful life for which the provider participated in Medicare. For purposes of this paragraph (f)(2)(i), scrapping refers to the physical removal from the provider's premises of tangible personal properties that are no longer useful for their intended purpose and are only salable for their scrap or junk value.

(ii) If the total amount of gains or losses realized from bona fide sales or scrapping does not exceed $5,000 within the cost reporting period or if the provider's cumulative utilization under the Medicare program is less than 5 percent, the net amount of gains or losses realized from sale or scrapping will be allowed as a depreciation adjustment in the period of disposal. For purposes of this paragraph (f)(2)(ii), the provider's cumulative Medicare utilization precentage is determined by comparing the cumulative total of the Medicare inpatient days for all reporting periods in which depreciation on the asset disposed of was claimed under the Medicare program to the cumulative total of inpatient days of the participating provider for the same reporting periods.

(iii) If the conditions specified in paragraph (f)(2)(ii) of this section are not met, the adjustment to reimbursable cost in the reporting period of asset disposition is calculated as follows:

(A) The total amount of gains or losses shall be allocated to all reporting periods under the Medicare program, based on the ratio of the depreciation allowed on the assets in each reporting period to the total depreciation allowed under the Medicare program.

(B) The results of this allocation are multiplied by the ratio of Medicare reimbursable cost to total allowable cost for each reporting period.

(C) The results of this multiplication are then added.

(D) Effective for cost reporting periods beginning on or after October 1, 1991, no adjustment will be made for the portion of gains or losses allocated to inpatient hospital services for which the hospital was paid under the fully prospective payment methodology as described in §412.340 of this chapter or under the hold-harmless methodology based on the Federal rate as described in §412.344(a)(1) of this chapter for new capital costs or in §412.344(a)(2) of this chapter.

(iv) If a provider sells more than one asset for a lump sum sales price, the gain or loss on the sale of each depreciable asset must be determined by allocating the lump sum sales price among all the assets sold, in accordance with the fair market value of each asset as it was used by the provider at the time of sale. If the buyer and seller cannot agree on an allocation of the sales price, or if they do agree but there is insufficient documentation of the current fair market value of each asset, the intermediary for the selling provider will require an appraisal by an independent appraisal expert to establish the fair market value of each asset and will make an allocation of the sales price in accordance with the appraisal.

(3) *Sale within 1 year after termination.* Gains and losses realized from a bona fide sale of depreciable assets within 1 year immediately following the date on which the provider terminates participation in the Medicare program are also included in the determination of allowable cost, in accordance with the procedure specified in paragraph (f)(2) of this section. However, if several assets are sold for a lump sum sales price, the determination of fair market value must be based on the appraised value of the assets as they were last

used by the provider while participating in the Medicare program.

(4) *Exchange, trade-in or donation.* Gains or losses realized from the exchange, trade-in, or donation of depreciable assets are not included in the determination of allowable cost. When the disposition of an asset is by means of exchange or trade-in, the historical cost of the new asset is the sum of the undepreciated cost of the asset disposed of and the additional cash or other assets transferred (or to be transferred) to acquire the new asset. However, if the asset disposed of was acquired by the provider before its participation in the Medicare program and the sum of the undepreciated cost and the cash or other assets transferred (or to be transferred) exceed the list price or fair market value of the new asset, the historical cost of the new asset is limited to the lower of its list price or fair market value.

(5) *Demolition or abandonment.* (i) For purposes of this section, the term ''abandonment'' means the permanent retirement of an asset for any future purpose, not merely the provider's ceasing to use the asset for patient care purposes. To claim an abandonment under the Medicare program, the provider must have relinquished all rights, title, claim, and possession of the asset with the intention of never reclaiming it or resuming its ownership, possession, or enjoyment.

(ii) If losses resulting from the demolition or abandonment of depreciable assets do not exceed $5,000 within the cost-reporting period, the losses are to be allowed in the period of disposal.

(iii) If losses exceed $5,000 and, at the date of disposition, the demolished or abandoned assets are at least 80 percent depreciated as computed under the straight-line method, such losses are includable in the determination of allowable cost under the Medicare program in the period of disposal and the procedure provided in paragraph (f)(2)(iii) of this section must be used in determining the adjustment to reimbursable cost.

(iv) Losses in excess of $5,000 resulting from the demolition or abandonment of assets, which at the date of disposition are not 80 percent depreciated as computed under the straight-line method, must be capitalized as a deferred charge and amortized as follows:

(A) If the State Health Planning and Development Agency (SHPDA) designated under section 1521 of the Public Health Service Act approves the demolition or abandonment of a depreciable asset as being consistent with the health systems plan of the health service area in which the provider is located, the net loss realized shall be capitalized as a deferred charge and amortized over the remaining life of the demolished or abandoned asset, or at the rate of $5,000 per year, whichever is greater. If no SHPDA exists or if such agency is unable or unwilling to perform this function, the provider must submit a request for approval to the intermediary. The intermediary, after reviewing this request and before issuing the approval, will submit the request along with its recommendation to the appropriate Regional Office for its approval.

(B) If a provider fails to obtain approval as specified in paragraph (f)(5)(iv)(A) of this section, a loss is not allowable unless the demolished or abandoned asset is replaced. If the asset is replaced, the loss resulting from the unapproved demolition or abandonment must be capitalized as a deferred charge and amortized over the estimated useful life of the replacement asset or at the rate of $5,000 per year, whichever is greater.

(v) If a loss resulting from the demolition or abandonment is deferred and amortized and the provider terminates its participation in the Medicare program or ceases to use a replacement asset in the provision of patient care services, the unamortized deferred charge remaining at that time must not be included in determining allowable cost under the Medicare program.

(vi) Losses on demolition must include the demolition cost incurred by the provider for razing and removal of the asset, less any salvage value recovered by the provider. However, if a provider demolishes a depreciable asset for the purpose of preparing land for future sale, the net demolition cost incurred by the provider (razing and removal

costs less salvage recovered) is considered a capital expenditure and added to the historical basis of the land.

(vii) If a provider purchases land on which there is a building, no depreciation will be allowed under the Medicare program unless the building is used in providing patient care. If the building is demolished, the entire purchase price and demolition cost shall be considered the historical cost of the land. If the building is used for patient care, but demolished within 5 years of purchase, the entire purchase price, less allowed depreciation, plus demolition cost will be considered the historical cost of the land.

(6) *Involuntary conversion.* (i) Losses resulting from the involuntary conversion of depreciable assets, such as condemnation, fire, theft, or other casualty, are generally included in the determination of allowable cost on a deferred basis if the asset is restored or replaced. However, losses resulting from a provider's imprudent management of its depreciable assets, such as the failure to obtain proper insurance coverage, are not included in the determination of allowable cost.

(ii) The net allowable loss from involuntary conversion must consist of the undepreciated cost of unrecovered book value of the asset, less amounts received from insurance proceeds gifts, and grants received from local, State, or Federal government, or any other source as a result of the involuntary conversion.

(iii) If the asset is replaced and the net allowable loss in any cost-reporting period does not exceed $5,000, the entire amount must be included in allowable cost in the period in which the loss is incurred. If the asset is replaced and the net allowable loss in any cost-reporting period exceeds $5,000, the loss must be capitalized as a deferred charge and amortized over the useful life of the replacement or restored asset. If a replaced or restored asset ceases to be used in the provision of patient care services or the provider terminates its participation in the Medicare program, the unamortized deferred charge remaining at that time will not be included in determining allowable cost under the Medicare program.

(iv) If the provider fails to replace or restore an involuntarily converted asset, the loss is not included in determining allowable cost. However, if the provider intends to replace or restore the asset but is unable to do so because the designated SHPDA finds such replacement or restoration to be inconsistent with the health systems plan of the provider's health service area, the loss is allowable so long as the provider continues to participate in Medicare. In this case, the loss must be capitalized as a deferred charge and amortized over the remaining life of the involuntarily converted asset, or at the rate of $5,000 per year, whichever is greater.

(v) If a gain is realized from an involuntary conversion of depreciable assets, the net amount realized reduces the basis of the restored or replacement asset. If the asset is not restored or replaced, the gain is to be treated in accordance with paragraph (f)(2) of this section.

(7) *Effect on equity capital.* The unrecovered loss entered on the books of the provider as a deferred charge, in accordance with paragraphs (f) (5) and (6) of this section, is not includable in the computation of equity capital under §413.157.

(8) *Sale of replacement or restored assets.* If a provider sells a replacement or restored asset while participating in the Medicare program or within 1 year immediately following the date on which it terminates its participation in the Medicare program, the unrecovered loss entered on the books of the provider as a deferred charge in accordance with paragraphs (f) (5) and (6) of this section will not be included in determining the gain or loss realized from the sale of the replacement or restored asset. However, if the sale of such asset is made to a related organization, as defined in §413.17, and the purchasing organization continues as a provider in the Medicare program, the remaining deferred charge representing the unrecovered depreciable basis of the demolished, abandoned or destroyed asset must continue to be amortized over the remaining expected useful life of the replacement or restored asset. If the sale is made to an

unrelated organization, further amortization of the deferred charge is not allowed.

(g) *Establishment of cost basis on purchase of facility as an ongoing operation*—(1) *Assets acquired after July 1, 1966 and before August 1, 1970.* The cost basis for the assets of a facility purchased as an ongoing operation after July 1, 1966, and before August 1, 1970, is the lowest of the—

(i) Total price paid for the facility by the purchaser, as allocated to the individual assets of the facility;

(ii) Total fair market value of the facility at the time of the sale, as allocated to the individual assets; or

(iii) Combined fair market value of the individually identified assets at the time of the sale.

(2) *Assets acquired after July 31, 1970 and, for hospitals and SNFs, before July 18, 1984.* For depreciable assets acquired after July 31, 1970 and, for hospitals and SNFs, before July 18, 1984, in addition to the limitations specified in paragraph (g)(1) of this section, the cost basis of the depreciable assets may not exceed the current reproduction cost depreciated on a straight-line basis over the life of the asset to the time of the sale.

(3) *Assets acquired by hospitals and SNFs on or after July 18, 1984 and not subject to an enforceable agreement entered into before that date.* Subject to paragraphs (b)(1)(ii) (B) through (G) and (b)(1)(iii) of this section, historical cost may not exceed the lowest of the following:

(i) The allowable acquisition cost of the asset to the owner of record as of July 18, 1984 (or, in the case of an asset not in existence as of July 18, 1984, the first owner of record of the asset);

(ii) The acquisition cost to the new owner; or

(iii) The fair market value of the asset on the date of acquisition.

(4) *Assets acquired by all providers on or after December 1, 1997.* Subject to the provisions of paragraph (b)(1)(i)(A) of this section, the historical cost may not exceed the historical cost of the asset, as recognized under the Medicare program, less depreciation allowed, to the owner of record as of August 5, 1997 (or for an asset not in existence as of August 5, 1997, the first owner of record after August 5, 1997).

(5) *Transactions other than bona fide.* If the purchaser cannot demonstrate that the sale was bona fide, in addition to the limitations specified in paragraph (g)(1), (2), and (3) of this section, the purchaser's cost basis may not exceed the seller's cost basis, less accumulated depreciation.

(h) *Sale and leaseback agreements and other lease transactions.* (1) For sale and leaseback agreements for all providers, and for sale and leaseback agreements for hospitals and SNFs entered into before October 23, 1992, a provider may include in its allowable costs incurred rental charges, as specified in a sale and leaseback agreement with a nonrelated purchaser involving plant facilities or equipment, only if—

(i) The rental charges are reasonable based on consideration of rental charges of comparable facilities and market conditions in the area; the type, expected life, condition, and value of the facilities or equipment rented; and other provisions of the rental agreement;

(ii) Adequate alternate facilities or equipment that would serve the purpose are not or were not available at lower cost; and

(iii) The leasing was based on economic and technical considerations.

(2) If the conditions of paragraph (h)(1) of this section are not met, the amount a provider may include in its allowable costs as rental or lease expense under a sale and leaseback agreement may not exceed the amount that the provider would have included in its allowable costs had the provider retained legal title to the facilities or equipment such as interest expense on mortgages, taxes, depreciation, and insurance costs.

(3) For hospitals and SNFs entering into sale and leaseback agreements on or after October 23, 1992, the amount a provider may include in its allowable costs as rental or lease expense may not exceed the amount that the provider would have included in its allowable costs had the provider retained legal title to the facilities or equipment, such as interest expense on mortgages, taxes, depreciation, and insurance costs (the costs of ownership).

This limitation applies both on an annual basis and over the useful life of the asset.

(i) If in the early years of the lease, the annual rental or lease costs are less than the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are more than the annual costs of ownership, in the years that the annual rental or lease costs are more than the costs of ownership the provider may include in allowable costs annually the actual amount of rental or lease costs. The aggregate rental or lease costs included in allowable costs may not exceed the aggregate costs of ownership that would have been included in allowable costs over the useful life of the asset had the provider retained legal title to the asset.

(ii) If in the early years of the lease, the annual rental or lease costs exceed the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are less than the annual costs of ownership, the provider may carry forward amounts of rental or lease costs that were not included in allowable costs in the early years of the lease due to the costs of ownership limitation, and include these amounts in allowable costs in the years of the lease when the annual rental or lease costs are less than the annual costs of ownership. In any given year the amount of actual annual rental or lease costs plus the amount carried forward to that year may not exceed the amount of the costs of ownership for that year.

(iii) In the aggregate, the amount of rental or lease costs included in allowable costs may not exceed the amount of the costs of ownership that the provider could have included in allowable costs had the provider retained legal title to the asset.

(4) For lease transactions of all providers entered into before October 23, 1992, a lease that meets the following conditions establishes a virtual purchase:

(i) The rental charge exceeds rental charges of comparable facilities or equipment in the area.

(ii) The term of the lease is less than the useful life of the facilities or equipment.

(iii) The provider has the option to renew the lease at a significantly reduced rental, or the provider has the right to purchase the facilities or equipment at a price that appears to be significantly less than what the fair market value of the facilities or equipment would be at the time acquisition by the provider is permitted.

(5)(i) If a lease is a virtual purchase under paragraph (h)(4) of this section, the rental charge is includable in allowable costs only to the extent that it does not exceed the amount that the provider would have included in allowable costs if it had legal title to the asset (the cost of ownership), such as straight-line depreciation, insurance, and interest. For purposes of computing the limitation on allowable rental cost in this paragraph, a provider may not include accelerated depreciation.

(ii) The difference between the amount of rent paid and the amount of rent allowed as rental expense is considered a deferred charge and must be capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner instead of being purchased, the deferred charge may be expensed in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be expensed to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be expensed to the extent of increasing the reduced rental to a fair rental value.

(6) For lease transactions entered into on or after October 23, 1992, a lease that meets any one of the following conditions establishes a virtual purchase:

(i) The lease transfers title of the facilities or equipment to the lessee during the lease term.

(ii) The lease contains a bargain purchase option.

(iii) The lease term is 75 percent or more of the useful life of the facilities or equipment. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment.

(iv) The present value of the minimum lease payments (that is, payments to be made during the lease term, including bargain purchase option, guaranteed residual value, or penalties for failure to renew) equals 90 percent or more of the fair market value of the leased property. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment. The present value is computed using the lessee's incremental borrowing rate, unless the interest rate implicit in the lease is known and is less than the lessee's incremental borrowing rate, in which case, the interest rate implicit in the lease is used.

(7)(i) If a lease is a virtual purchase under paragraph (h)(6) of this section, the rental charge is includable in allowable costs only to the extent that it does not exceed the amount that the provider would have included in allowable costs if it had legal title to the asset (the costs of ownership), such as straight-line depreciation, insurance, and interest. For purposes of computing the limitation on allowable rental cost as described in this paragraph, a provider may not include accelerated depreciation in its allowable costs.

(ii) The difference between the amount of rent paid and the amount of rent allowed as rental expense is considered a deferred charge and is capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner instead of being purchased, the deferred charge may be expensed in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be expensed to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be expensed to the extent of increasing the reduced rental to a fair rental value.

(vi) If the lessee becomes the owner of the leased asset (either by operation of the lease or by other means), the amount considered as depreciation, for the purpose of having computed the limitation expressed in paragraph (h)(7)(i) of this section, must be used in calculating the limitation on adjustments to depreciation for the purpose of determining any gain or loss upon disposal of an asset under paragraph (f) of this section.

(i) *Intergovernmental transfer of facilities*. The basis for depreciation of assets transferred under appropriate legal authority from one governmental entity to another is as follows:

(1) The historical cost incurred by the present owner in acquiring the asset under a bona fide sale. The historical cost may not exceed the lower of current reproduction cost adjusted for straight-line depreciation over the life of the asset to the time of the purchase of fair market value at the time of the purchase.

(2) The fair market value at the time of donation under a bona fide donation of the asset (subject to the limitations set forth under paragraph (i) of this section). An asset is considered donated when a governmental entity acquires the asset without assuming the functions for which the transferor used the asset or making any payment for it in the form of cash, property, or services.

(3) If neither paragraph (h) (1) nor (2) of this section applies, for example, the transfer was solely to facilitate administration or to reallocate jurisdictional responsibility, or the transfer constituted a taking over in whole or in part of the function of one governmental entity by another governmental entity, the basis for depreciation is—

(i) With respect to an asset on which the transferor has claimed depreciation under the Medicare program, the transferor's basis under the Medicare program prior to the transfer. The method of depreciation used by the transferee may be the same as that used by the

transferor, or the transferee may change the method, as permitted under paragraph (d)(2) of this section; or

(ii) With respect to an asset on which the transferor has not claimed depreciation under the Medicare program, the cost incurred by the transferor in acquiring the asset (not to exceed the basis that would have been recognized had the transferor participated in the Medicare program) less depreciation calculated on the straight-line basis over the life of the asset to the time of transfer.

(j) *Basis of assets donated to a provider*—(1) Assets not used or depreciated under the Medicare program. If an asset has never been used or depreciated under the Medicare program and is donated to a provider, the basis for the purpose of calculating depreciation and equity capital (if applicable) is the fair market value of the asset at the time of donation.

(2) *Assets used or depreciated under the Medicare program.* If an asset has been used or depreciated under the Medicare program and is donated to a provider, the basis for the purpose of calculating depreciation and equity capital (if applicable) is the lesser of—

(i) The fair market value at the time of donation; or

(ii) The net book value in the hands of the owner last participating in the Medicare program.

(3) *Transfers of State hospitals to nonprofit corporations without monetary consideration.* If a State transfers a hospital to a nonprofit corporation without monetary consideration on or after July 18, 1984, the depreciable basis of the assets to the new owner is the net book value of the assets as recorded on the State's books at the time of the transfer. For purposes of this section, monetary consideration includes cash, new debt, and assumed debt.

(k) *Transactions involving a provider's capital stock*—(1) *Acquisition of capital stock of a provider.* If the capital stock of a provider is acquired, the provider's assets may not be revalued. For example, if Corporation A purchases the capital stock of Corporation B, the provider, Corporation B continues to be the provider after the purchase and Corporation A is merely the stockholder. Corporation B's assets may not be revalued.

(2) *Statutory merger.* A statutory merger is a combination of two or more corporations under the corporation laws of the State, with one of the corporations surviving. The surviving corporation acquires the assets and liabilities of the merged corporation(s) by operation of State law. The effect of a statutory merger upon Medicare reimbursement is as follows:

(i) *Statutory merger between unrelated parties.* If the statutory merger is between two or more corporations that are unrelated (as specified in §413.17), the assets of the merged corporation(s) acquired by the surviving corporation may be revalued in accordance with paragraph (g) of this section. If the merged corporation was a provider before the merger, then it is subject to the provisions of paragraphs (d)(3) and (f) of this section concerning recovery of accelerated depreciation and the realization of gains and losses. The basis of the assets owned by the surviving corporation are unaffected by the transaction. An example of this type of transaction is one in which Corporation A, a nonprovider, and Corporation B, the provider, are combined by a statutory merger, with Corporation A being the surviving corporation. In such a case the assets of Corporation B acquired by Corporation A may be revalued in accordance with paragraph (g) of this section.

(ii) *Statutory merger between related parties.* If the statutory merger is between two or more related corporations (as specified in §413.17), no revaluation of assets is permitted for those assets acquired by the surviving corporation. An example of this type of transaction is one in which Corporation A purchase the capital stock of Corporation B, the provider. Immediately after the acquisition of the capital stock of Corporation B, there is a statutory merger of Corporation B and Corporation A, with Corporation A being the surviving corporation. Under these circumstances, at the time of the merger the transaction is one between related parties and is not a basis for revaluation of the provider's assets.

(3) *Consolidation.* A consolidation is the combination of two or more corporations resulting in the creation of a new corporate entity. If at least one of the original corporations is a provider, the effect of a consolidation upon Medicare reimbursement for the provider is as follows:

(i) *Consolidation between unrelated parties.* If the consolidation is between two or more corporations that are unrelated (as specified in § 413.17), the assets of the provider corporation(s) may be revalued in accordance with paragraph (g) of this section.

(ii) *Consolidation between related parties.* If the consolidation is between two or more related corporations (as specified in § 413.17), no revaluation of provider assets is permitted.

[51 FR 34793, Sept. 30, 1986, as amended at 56 FR 43456, Aug. 30, 1991; 57 FR 3017, Jan. 27, 1992; 57 FR 39830, Sept. 1, 1992; 57 FR 43919, Sept. 23, 1992; 58 FR 17528, Apr. 5, 1993; 59 FR 45401, Sept. 1, 1994; 63 FR 1382, Jan. 9, 1998; 65 FR 8662, Feb. 22, 2000]

§ 413.139 Depreciation: Optional allowance for depreciation based on a percentage of operating costs.

(a) *Principle.* With respect to all assets acquired before 1966, the provider, at its option, may choose an allowance for depreciation based on a percentage of operating costs. The operating costs to be used are the provider's 1965 operating costs or the provider's current year's allowable costs, whichever are the lower. The percentage to be applied is 5 percent starting with the year 1966–67, with such percentage being uniformly reduced by one-half percent each succeeding year. The allowance based on operating costs is in addition to regular depreciation on assets acquired after 1965; however, if the optional allowance is selected, the combined amount of such allowance on pre-1966 assets and the straight-line depreciation on assets acquired after 1965 (including the estimated depreciation on assets held on a rental basis during the current year) may not exceed 6 percent of the provider's allowable cost for the current year.

(b) *Definitions*—(1) *Operating costs.* Operating costs are the total costs incurred by the provider in operating the institution or facility.

(2) *Allowable costs.* Allowable costs are the costs of a provider that are includable under the principles for cost reimbursement. Through application of apportionment methods to the total amount of such allowable costs, the share of a provider's total cost that is attributable to covered services for beneficiaries is determined.

(c) *Application.* If a provider has inadequate historical cost records for pre-1966 depreciable assets, the provider may elect to receive an allowance for depreciation on such assets based on a percentage of operating costs. The optional allowance for depreciation for such assets may be used, however, whether or not a provider has records of the cost of pre-1966 depreciable assets currently in use.

(d) *Allowance based on a percentage of operating costs.* (1) The allowance for depreciation based on a percentage of operating costs is to be computed by applying a specified percentage to a base amount equal to the provider's 1965 total operating costs, without adjustments to these principles or the current year's allowable operating costs, whichever is lower. The percentage to be applied is five for the reporting period that starts before or during 1966–67, four and one-half for the reporting period that begins during 1967–68, and continues to decline annually by equal amounts to become zero in 1976–77.

(2) If used as a base for determining the optional allowance for depreciation, neither the 1965 operating costs nor the current year's allowable costs are to include any actual depreciation, estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, or return on equity capital. Such exclusions are to be made only for the purpose of computing the allowance for depreciation based on operating costs. For other purposes, the excluded amounts are recognized in determining allowable costs and for computing the costs of services furnished to Medicare beneficiaries during the reporting period.

(e) *Change to actual depreciation.* (1) A provider that elects this allowance may at any time before 1976 change to

actual depreciation on all pre-1966 depreciable assets. In such case, this option is eliminated and the provider can no longer elect to receive an allowance for depreciation based on a percentage of operating costs.

(2) If the provider desires to change to actual depreciation but either has no historical cost records or has incomplete records, the determination of historical cost may be made through appropriate means involving expert consultation with the determination being subject to review and approval by the intermediary.

(f) *Determination of optional allowance based on percentage of operating costs illustrated.* The following illustrates how the provider would determine the optional allowance for depreciation based on operating costs.

Example No. 1. The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 do not include any actual depreciation or rentals on depreciable-type assets. The current year's allowable cost also does not include any allowance in lieu of specific recognition of other costs or return on equity capital.

YEAR 1966

Current year's allowable cost	$1,100,000
Operating cost for 1965[1]	$1,000,000
Percent for determining the allowance	5
Allowance	$50,000

[1] 1965 Operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

YEAR 1967

Current year's allowable cost	$1,200,000
Operating cost for 1965[1]	$1,000,000
Percent for determining the allowance[2]	5
Allowance	$50,000

[1] 1965 Operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1967 allowable cost.

[2] Since the reporting period began during the year 1966–1967 (July 1, 1966–June 30, 1967) 5 percent is the percentage to be used.

YEAR 1968

Operating cost for 1965	$1,000,000
Current year's allowable cost[1]	$900,000
Percent for determining the allowance[2]	4½
Allowance	$40,500

[1] The current year's allowable cost was used in computing the allowance for depreciation based on percentage of operating costs because it was lower than 1965 operating cost.

[2] Since the reporting period began during the year 1967–1968 (July 1, 1967–June 30, 1968) 4½ percent is the percentage to be used.

Example No. 2. When the provider pays rent for depreciable-type assets rented prior to 1966, the estimated depreciation on such assets must be deducted from the allowance. The following illustration demonstrates how the allowance is determined.

The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 did not include any actual depreciation, allowance in lieu of specific recognition of other costs, or return on equity capital. However, such costs have been adjusted to exclude estimated depreciation on rented depreciable-type assets.

YEAR 1966

Adjusted current year's allowable cost	$1,100,000
Adjusted operating cost for 1965[1]	$1,000,000
Percent for determining the allowance	5
Allowance	$50,000
Less estimated depreciation for depreciable-type assets rented prior to 1966 on which rental is paid in 1966	$3,000
Adjusted allowance	$47,000

[1] 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

(g) *Limitation on depreciation if optional allowance is used.* This optional allowance only is subject to a limitation based on the provider's total allowable operating cost for the current year. To determine this limitation, compute the sum of the actual depreciation claimed, the allowance based on a percentage of operating costs, and the estimated straight-line depreciation on depreciable-type assets rented after 1965. If this sum exceeds six percent of the provider's current year's allowable cost (exclusive of any actual depreciation claimed, estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital), the allowance for depreciation based on a percentage of operating costs is reduced by the amount of excess. In applying this limitation, if the actual depreciation claimed is on an accelerated basis, it must be converted to a straight-line basis only for use in calculating this limitation. It is presumed that pre-1966 assets will not be retired at a greater than normal rate, and the limitation of six percent, as it affects the availability of the allowance, is designed as a safeguard if the presumption is not borne out. If

the provider does not elect to use the optional allowance, the combined allowance for depreciation based on costs of pre-1966 assets and those subsequently acquired is not subject to the six percent limitation.

Example No. 1. The following illustration demonstrates how this limitation would be determined.

YEAR 1966

[The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 have been adjusted to exclude actual depreciation, the estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital.]

Adjusted operating cost for 1965	$1,000,000
Percent for determining the allowance	5
In 1966 assets were acquired which produce a straight-line depreciation of	$18,000
Estimated depreciation on assets rented in 1966	$2,000
Adjusted allowable operating cost for 1966	$1,100,000

CALCULATION OF ALLOWANCE FOR DEPRECIATION BASED ON A PERCENTAGE OF OPERATING COSTS

Gross allowance	
5 percent times adjusted 1965 operating costs ($1,000,000)	$50,000
Estimated depreciation on assets rented in 1966	2,000
Straight-line depreciation on post-1965 assets	18,000
Total	70,000
6 percent of adjusted 1966 allowable operating cost	66,000
Reduction in allowance	4,000
Allowance	50,000
Reduction	4,000
Adjusted allowance	46,000
Total depreciation allowance for 1966 ($18,000 actual depreciation plus $46,000 allowance based on operating cost)	64,000

Assume in this illustration that the provider had elected to use the declining balance method in computing its allowable depreciation and the rental expense for depreciable-type assets was $3,500. In that case, it would include in its 1966 allowable cost not only the $46,000 allowance based on operating costs but also $36,000 (in this instance 2×straight-line rate is used) in actual depreciation and the rental expense of $3,500—or a total of $85,500 covering all its depreciable assets.

§ 413.144 Depreciation: Allowance for depreciation on fully depreciated or partially depreciated assets.

(a) *Principle.* Depreciation on assets being used by a provider at the time it enters into the Medicare program is allowed. This principle applies even though such assets may be fully or partially depreciated on the provider's books.

(b) *Application.* Depreciation is allowable on assets being used at the time the provider enters into the program. This applies even though such assets may be fully depreciated on the provider's books or fully depreciated with respect to other third-party payers. So long as an asset is being used, its useful life is considered not to have ended, and consequently the asset is subject to depreciation based upon a revised estimate of the asset's useful life as determined by the provider and approved by the intermediary. Correction of prior years' depreciation to reflect revision of estimated useful life should be made in the first year of participation in the program unless the provider has used the optional method (§ 413.139), in which case the correction should be made at the time of discontinuing the use of that method. If an asset has become fully depreciated under Medicare, further depreciation is not appropriate or allowable, even though the asset may continue in use.

(c) *Example of an allowance for a fully-depreciated asset.* For example, if a 50-year-old building is in use at the time the provider enters into the program, depreciation is allowable on the building even though it has been fully depreciated on the provider's books. Assuming that a reasonable estimate of the asset's continued life is 20 years (70 years from the date of acquisition), the provider may claim depreciation over the next 20 years—if the asset is in use that long—or a total depreciation of as much as twenty-seventieths of the asset's historical cost.

(d) *Corrections to depreciation.* If the asset is disposed of before the expiration of its estimated useful life, the depreciation would be adjusted to the actual useful life. Likewise, a provider may not have fully depreciated other assets it is using and finds that it has incorrectly estimated the useful lives of those assets. In such cases, the provider may use the corrected useful lives in determining the amount of depreciation, provided such corrections have been approved by the intermediary.

§ 413.149 Depreciation: Allowance for depreciation on assets financed with Federal or public funds.

(a) *Principle*. Depreciation is allowed on assets financed with Hill-Burton or other Federal or public funds.

(b) *Application*. Like other assets (including other donated depreciable assets), assets financed with Hill-Burton or other Federal or public funds become a part of the provider institution's plant and equipment to be used in furnishing services. It is the function of payment of depreciation to provide funds that make it possible to maintain the assets and preserve the capital employed in the production of services. Therefore, irrespective of the source of financing of an asset, if it is used in the providing of services for beneficiaries of the program, payment for depreciation of the asset is, in fact, a cost of the production of those services. Moreover, recognition of this cost is necessary to maintain productive capacity for the future. An incentive for funding of depreciation is provided in these principles by the provision that investment income on funded depreciation is not treated as a reduction of allowable interest expense under § 413.153(a).

§ 413.153 Interest expense.

(a)(1) *Principle*. Necessary and proper interest on both current and capital indebtedness is an allowable cost. However, interest costs are not allowable if incurred as a result of—

(i) Judicial review by a Federal court (as described in § 413.64(j));

(ii) An interest assessment on a determined overpayment (as described in § 405.377 of this chapter); or

(iii) Interest on funds borrowed to repay an overpayment (as described in § 413.64(j) or § 405.378 of this chapter), up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (for example, capital improvements).

(2) *Exception*. In those cases of administrative or judicial reversal, interest paid on funds borrowed to repay an overpayment is an allowable cost, in accordance with this section.

(b) *Definitions*—(1) *Interest*. Interest is the cost incurred for the use of borrowed funds. Interest on current indebtedness is the cost incurred for funds borrowed for a relatively short term. This is usually for such purposes as working capital for normal operating expenses. Interest on capital indebtedness is the cost incurred for funds borrowed for capital purposes, such as acquisition of facilities and equipment, and capital improvements. Generally, loans for capital purposes are long-term loans.

(2) *Necessary*. Necessary interest is interest that meets the following requirements:

(i) It is incurred on a loan made to satisfy a financial need of the provider. Loans that result in excess funds or investments are not considered necessary.

(ii) It is incurred on a loan made for a purpose reasonably related to patient care.

(iii) It is reduced by investment income except income from—

(A) Gifts, grants, and endowments, whether held separately or pooled with other funds;

(B) Funded depreciation that meets the program's qualifying criteria;

(C) The provider's qualified pension funds;

(D) The provider's deferred compensation funds that meet the program's qualifying criteria; and

(E) The provider's self-insurance trust funds that meet the program's qualifying criteria.

(iv) It is not reduced by interest received as a result of judicial review by a Federal court (as described in § 413.64(j)).

(3) *Proper*. Proper requires that interest be—

(i) Incurred at a rate not in excess of what a prudent borrower would have had to pay in the money market existing at the time the loan was made; and

(ii) Paid to a lender not related through control or ownership, or personal relationship to the borrowing organization. However, interest is allowable if paid on loans from the provider's donor-restricted funds, the funded depreciation account, or the provider's qualified pension fund.

(4) *Zero coupon bonds*. Zero coupon bonds are issued by government agencies, corporations, and banks at a price

substantially below the face value. The difference between the purchase price and the face value reflects the actual amount of interest and is neither a discount nor an adjustment to the interest rate as with other bonds. Interest is paid at maturity when the bond is redeemed at face value.

(c) *Borrower-lender relationship.* (1) Except as described in paragraph (c)(2) of this section, to be allowable, interest expense must be incurred on indebtedness established with lenders or lending organizations not related through control, ownership, or personal relationship to the borrower. Presence of any of these factors could affect the ''bargaining'' process that usually accompanies the making of a loan, and could thus be suggestive of an agreement on higher rates of interest or of unnecessary loans. Loans should be made under terms and conditions that a prudent borrower would make in armslength transactions with lending institutions. The intent of this provision is to assure that loans are legitimate and needed, and that the interest rate is reasonable. Thus, interest paid by the provider to partners, stockholders, or related organizations of the provider would not be allowable. If the owner uses his own funds in a business, it is reasonable to treat the funds as invested funds or capital, rather than borrowed funds. Therefore, if interest on loans by partners, stockholders, or related organizations is disallowed as a cost solely because of the relationship factor, the principal of such loans is treated as invested funds in the computation of the provider's equity capital under § 413.157.

(2) Exceptions to the general rule regarding interest on loans from controlled sources of funds are made in the following circumstances. Interest on loans to providers by partners, stockholders, or related organizations made prior to July 1, 1966, is allowable as cost, provided that the terms and conditions of payment of such loans have been maintained in effect without modification subsequent to July 1, 1966. If the general fund of a provider ''borrows'' from a donor-restricted fund and pays interest to the restricted fund, this interest expense is an allowable cost. The same treatment is accorded interest paid by the general fund on money ''borrowed'' from the funded depreciation account of the provider or from the provider's qualified pension fund. In addition, if a provider operated by members of a religious order borrows from the order, interest paid to the order is an allowable cost.

(3) If funded depreciation is used for purposes other than improvement, replacement, or expansion of facilities or equipment related to patient care, allowable interest expense is reduced to adjust for offsets not made in prior years for earnings on funded depreciation. A similar treatment is accorded deposits in the provider's qualified pension fund if such deposits are used for other than the purpose for which the fund was established.

(d) *Loans not reasonably related to patient care.* (1) The following types of loans are not considered to be for a purpose reasonably related to patient care:

(i) For loans made to finance acquisition of a facility, that portion of the cost that exceeds—

(A) Historical cost as determined under § 413.134(b); or

(B) The cost basis determined under § 413.134(g); and

(ii) Loans made to finance capital stock acquisitions, mergers, or consolidations for which revaluation of assets is not allowed under § 413.134(k).

(2) In determining whether a loan was made for the purpose of acquiring a facility, we apply any owner's investment or funds first to the tangible assets, then to the intangible assets other than goodwill, and lastly to the goodwill. If the owner's investment or funds are not sufficient to cover the cost allowed for tangible assets, we apply funds borrowed to finance the acquisition to the portion of the allowed cost of the tangible assets not covered by the owner's investment, then to the intangible assets other than goodwill, and lastly to the goodwill. Repayments of the funds borrowed are applied first to the borrowing related to the tangible assets, then to the borrowing related to the intangible assets other than goodwill, and lastly to the borrowing related to the goodwill.

(3) When a provider borrows funds, but only some of the funds are necessary, repayments of the loan (principal and interest portions) are applied first to pay for the necessary portion of the loan. Only after all of the necessary portion of the loan (principal and interest) has been repaid are any repayments applied to the unnecessary portion of the loan. Repayments toward non-allowable borrowing pertaining to assets or activities not related to patient care are considered investments, and the provisions of paragraph (b)(2)(iii) of this section are applied.

(e) *Zero coupon bonds*—(1) *Interest on bonds issued on or after August 15, 1996.* For zero coupon bonds issued on or after August 15, 1996, interest expense incurred to provide funds for patient care-related costs is an allowable expense, and interest income earned for investment purposes is an allowable offset, in the cost reporting period in which the interest accrues.

(2) *Interest income offset.* Interest income from zero coupon bonds must be offset against allowable interest expense as prescribed in paragraph (b)(2) of this section and in §413.130(g)(2). If zero coupon bonds are purchased with the proceeds of an advanced refunding of debt, offset of the investment income is required under §413.153(b)(2)(iii), but the investment income is not prorated under §413.130(g)(2).

(3) *Use of effective interest method.* (i) Interest expense and interest income from zero coupon bonds that are reported as they accrue must be amortized using the effective interest method. This method recognizes the actual accrual of interest expense or income for each interest computation period (as specified by the bond instrument) throughout the life of the bond.

(ii) A constant effective yield rate is determined and applied to the book value (outstanding loan balance including prior accrued interest) of the bond at the beginning of each period to determine the total interest for the period.

(iii) If the interest computation period involves portions of more than one cost reporting period, the amount of interest for that computation period shall be apportioned to each cost reporting period.

(iv) An example of the computation of interest using the effective interest method follows:

Facts

Life of zero coupon bond: 15 years.

Value at maturity: $50,000.

Bondholder pays $6,996 for the bond.

Annual interest rate is 13.5506% compounded semi-annually.

From the table below, interest for the first year would be $980.11 ($474.00 plus $506.11).

Col 1 Six-month periods	Col 2 Book value beginning of period	Col. 3 Effective interest*	Col. 4 Book value end of period (columns 2 + 3)
1	$6,996.00	$474.00	$7,470.00
2	7,470.00	506.11	7,976.11
3	7,976.11	540.40	8,516.51
4	8,516.51	577.02	9,093.53
29	43,855.94	2,971.37	46,827.31
30	46,827.31	3,172.69	50,000.00

*Computed by multiplying the book value at the beginning of each period (Column 2) by 6.7753% (the annual interest rate of 13.5506% 2 = 6.7753%).

[51 FR 34793, Sept. 30, 1986, as amended at 56 FR 43457, Aug. 30, 1991; 59 FR 45402, Sept. 1, 1994; 61 FR 37014, July 16, 1996; 61 FR 63748, 63479, Dec. 2, 1996; 65 FR 8662, Feb. 22, 2000]

§413.157 Return on equity capital of proprietary providers.

(a) *Definitions.* For purposes of this section—

Proprietary provider means a provider that is organized and operated with the expectation of earning a profit for its owners (as distinguished from a provider that is organized and operated on a nonprofit basis). Proprietary providers may be sole proprietorships, partnerships, or corporations. Effective for cost reporting periods beginning on or after July 6, 1987, the term applies only to proprietary hospitals and SNFs.

(b) *General rule.* A reasonable return on equity capital invested and used in the provision of patient care is paid as an allowance in addition to the reasonable cost of covered services furnished to beneficiaries by proprietary providers.

(1) *Rate of return applicable to proprietary providers for cost reporting periods beginning before July 6, 1987.* Except as provided in paragraphs (b)(2), (b)(3),

and (b)(4) of this section, the amount allowable on an annual basis, for cost reporting periods beginning before July 6, 1987, is determined by multiplying the provider's equity capital by a percentage equal to one and one-half times the average of the rates of interest on special issues of public debt obligations issued for purchase by the Medicare Part A Trust Fund for each of the months during the provider's reporting period or portion thereof covered under the program.

(2) *Rate of return for inpatient hospital services furnished by proprietary hospitals.* The rate used in determining the return for inpatient hospital services is a percentage of the average of the rates of interest described in paragraph (b)(1) of this section. The percentages applicable to inpatient hospital services are as follows:

(i) 150 percent for cost reporting periods beginning before April 20, 1983.

(ii) 100 percent for cost reporting periods beginning on or after April 20, 1983 and before October 1, 1986.

(iii) 75 percent for cost reporting periods beginning on or after October 1, 1986 and before October 1, 1987.

(iv) 50 percent for cost reporting periods beginning on or after October 1, 1987 and before October 1, 1988.

(v) 25 percent for cost reporting periods beginning on or after October 1, 1988 and before October 1, 1989.

(vi) Zero percent for cost reporting periods beginning on or after October 1, 1989.

(3) *Rate of return related to proprietary SNFs.* (i) For cost reporting periods beginning on or after October 1, 1985, the rate used in determining the return for SNF services furnished before October 1, 1993, is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) There is no allowance for return for SNF services furnished on or after October 1, 1993.

(4) *Rate of return related to outpatient hospital services.* (i) For cost reporting periods beginning on or after October 1, 1985, the rate used in determining the return for outpatient hospital services furnished before January 1, 1988 is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) There is no allowance for return for outpatient hospital services furnished on or after January 1, 1988.

(5) *Rate of return for proprietary services of all nonhospital and non-SNF providers.* (i) For cost reporting periods beginning on or after October 1, 1985, but before July 6, 1987, the rate used in determining the return for services of all nonhospital and non-SNF providers is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) For cost reporting periods beginning on or after July 6, 1987, there is no allowance for return on equity capital for nonhospital and non-SNF providers.

(c) *Application*—(1) *Computation of equity capital.* For purposes of computing the allowable return, the provider's equity capital means—

(i) The provider's investment in plant, property, and equipment related to patient care (net of depreciation) and funds deposited by a provider who leases plant, property, or equipment related to patient care and is required by the terms of the lease to deposit such funds (net of noncurrent debt related to such investment or deposited funds); and

(ii) Net working capital maintained for necessary and proper operation of patient care activities. However, debt representing loans from partners, stockholders, or related organizations on which interest payments would be allowable as costs but for the provisions of § 413.153(b)(3)(ii), is not subtracted in computing the amount of equity capital in order that the proceeds from such loans be treated as part of the provider's equity capital. In computing the amount of equity capital upon which a return is allowable, investment in facilities is recognized on the basis of the historical cost, or other basis, used for depreciation and other purposes under Part A of Medicare.

(2) *Acquisitions after July 1970.* With respect to a facility or any tangible assets of a facility acquired on or after August 1, 1970, the excess of the price paid for such facility or such tangible assets over the historical cost, as defined in § 413.134(b), or the cost basis, as determined under § 413.134(g) (whichever is appropriate), is not includable

in equity capital, and loans made to finance such excess portion of the cost of such acquisitions (see §413.153(d)) are excluded in computing equity capital.

(3) *Acquisitions prior to August 1970.* With respect to a facility or any tangible assets of a facility acquired before August 1970, the excess of the price paid for such facility or assets over the fair market value of tangible assets at the time of purchase is includable in equity capital to the extent that it is reasonable except that the cumulative allowable return for such excess may not exceed 100 percent of such excess. For purposes of this section, the cumulative allowable return means the sum of the allowable rate of return on equity capital for all months starting from August 1, 1970. For example, if the allowable rates of return on equity capital for a provider are 9 percent for the first year (and such year started August 1, 1970), 8.5 percent for the second year, and 10.5 percent for the third year, the cumulative allowable return at the end of the third year would be 28 percent. After the cumulative allowable return equals 100 percent, the inclusion in equity capital of the excess is no longer allowable.

(4) *Computation of return on equity capital.* For purposes of computing the allowable return, the amount of equity capital is the average investment during the reporting period. The rate of return allowed, as derived from time to time based upon interest rates in accordance with this principle, is determined by CMS and communicated through intermediaries. Return on investment as an element of allowable costs is subject to apportionment in the same manner as other elements of allowable costs.

Example of calculation of cumulative allowable return. X purchased a provider on July 1, 1969, paying $100,000 in excess f the fair market value of the assets acquired. Provider X files its cost report on a calendar-year basis. The allowable rate of return on equity capital for August 1, 1970-December 31, 1970 (4.538 percent), is obtained by multiplying the allowable rate of return for the period ending December 31, 1970 (10.891) by 5/12 (a fraction of which the numerator is the number of months from August 1, 1970, to the end of the cost-reporting period and the denominator is the number of months in the cost-reporting period). The cumulative allowable return for Provider X for the period August 1, 1970-December 31, 1973, (32.367 percent) is computed as follows:

Cost reporting year ending	Rate of return on equity capital (percent)
Dec. 31, 1970	4.538
Dec. 31, 1971	8.969
Dec. 31, 1972	8.891
Dec. 31, 1973	9.969
Total	32.367

(The $100,000 paid in excess of the fair market value of the assets acquired is included in equity capital until the sum of the allowable rate of return on equity capital equals 100 percent. Of course, no portion of the $100,000 may be amortized as an allowable cost or is otherwise allowable for any program reimbursement purposes other than for determining the provider's equity capital.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987; 52 FR 32921, Sept. 1, 1987; 53 FR 12017, Apr. 12, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 26960, May 25, 1994]

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services and Organ Procurement Costs

SOURCE: 62 FR 43668, Aug. 15, 1997, unless otherwise noted.

§413.170 Scope.

This subpart implements sections 1881 (b)(2) and (b)(7) of the Act by—

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis furnished in or under the supervision of an ESRD facility approved under subpart U of part 405 of this chapter (referred to as ''facility'' in this section). For purposes of this section and §413.172 through §413.198, ''outpatient maintenance dialysis'' means outpatient dialysis, home dialysis, self-dialysis, and home dialysis training, as defined in §405.2102 (f)(2)(ii), (f)(2)(iii), and (f)(3) of this chapter, and includes all items and services specified in §§410.50 and 410.52 of this chapter.

(b) Providing procedures and criteria under which a facility may receive an

exception to the prospective payment rates; and

(c) Establishing procedures that a facility must follow to appeal its payment amount under the prospective payment system.

§ 413.172 Principles of prospective payment.

(a) Payments for outpatient maintenance dialysis are based on rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered outpatient maintenance dialysis.

(c) CMS publishes the methodology used to establish payment rates and the changes specified in § 413.196(b) in the FEDERAL REGISTER.

§ 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based facilities and independent ESRD facilities;

(2) Effectively encourages efficient delivery of dialysis services; and

(3) Provides incentives for increasing the use of home dialysis.

(b) *Determination of independent facility.* For purposes of rate-setting and payment under this section, CMS considers any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph (b) is an initial determination under § 498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination under § 498.3 of this chapter. For purposes of rate-setting and payment under this section, CMS determines that a facility is hospital-based if the—

(1) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(2) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;

(3) Facility personnel policies and practices conform to those of the hospital;

(4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, CMS does not consider—

(1) An agreement between a facility and a hospital concerning patient referral;

(2) A shared service arrangement between a facility and a hospital; or

(3) The physical location of a facility on the premises of a hospital.

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in § 414.313(c) of this chapter), the prospective rate (as described in paragraph (a) of this section) paid to that facility is increased by an add-on amount as described in § 414.313.

(f) *Erythropoietin/Epoietin (EPO).* (1) When EPO is furnished to an ESRD patient by a Medicare-approved ESRD facility or a supplier of home dialysis equipment and supplies, payment is based on the amount specified in paragraph (f)(3) of this section.

(2) The payment is made only on an assignment basis, that is, directly to the facility or supplier, which must accept, as payment in full, the amount that CMS determines.

(3) CMS determines the payment amount in accordance with the following rules:

(i) The amount is prospectively determined, as specified in section 1881(b)(11)(B)(ii) of the Act, reviewed and adjusted by CMS, as necessary, and

paid to hospital-based and independent dialysis facilities and to suppliers of home dialysis equipment and supplies, regardless of the location of the facility, supplier, or patient.

(ii) If CMS determines that an adjustment to the payment amount is necessary, CMS publishes a FEDERAL REGISTER notice proposing a revision to the EPO payment amount and requesting public comment.

(iii) Any increase in this amount for a year does not exceed the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(iv) The Medicare payment amount is subject to the Part B deductible and coinsurance.

(g) *Additional payment for certain drugs.* In addition to the prospective payment described in this section, CMS makes an additional payment for certain drugs furnished to ESRD patients by a Medicare-approved ESRD facility. CMS makes this payment directly to the ESRD facility. The facility must accept the allowance determined by CMS as payment in full. Payment for these drugs is made as follows:

(1) *Hospital-based facilities.* CMS makes payments in accordance with the cost reimbursement rules set forth in this part.

(2) *Independent facilities.* CMS makes payment in accordance with the methodology set forth in §405.517 of this chapter for paying for drugs that are not paid on a cost or prospective payment basis.

§413.176 Amount of payments.

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, the intermediary pays the facility 80 percent of its prospective payment rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, the intermediary subtracts the amount applicable to the deductible from the facility's prospective rate and pays the facility 80 percent of the remainder, if any.

§413.178 Bad debts.

(a) CMS will reimburse each facility its allowable Medicare bad debts, as defined in §413.89(b), up to the facility's costs, as determined under Medicare principles, in a single lump sum payment at the end of the facility's cost reporting period.

(b) A facility must attempt to collect deductible and coinsurance amounts owed by beneficiaries before requesting reimbursement from CMS for uncollectible amounts. Section 413.89 specifies the collection efforts facilities must make.

(c) A facility must request payment for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list that specifically enumerates all uncollectable amounts related to covered services under the composite rate.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 47489, Aug. 12, 2005]

§413.180 Procedures for requesting exceptions to payment rates.

(a) *Outpatient maintenance dialysis payments.* All payments for outpatient maintenance dialysis furnished at or by facilities are made on the basis of prospective payment rates.

(b) *Criteria for requesting an exception.* If a facility projects on the basis of prior year costs and utilization trends that it will have an allowable cost per treatment higher than its prospective rate set under §413.174, and if these excess costs are attributable to one or more of the factors in §413.182, the facility may request, in accordance with paragraph (d) of this section, that CMS approve an exception to that rate and set a higher prospective payment rate. However, a facility may only request an exception or seek to retain its previously approved exception rate when authorized under the conditions specified in paragraphs (d) and (e) of this section.

(c) *Application of deductible and coinsurance.* The higher payment rate is subject to the application of deductible and coinsurance in accordance with §413.176.

(d) *Payment rate exception request.* A facility must request an exception to its payment rate within 180 days of—

(1) The effective date of its new composite payment rate(s);

(2) The effective date that CMS opens the exceptions process; or

(3) The date on which an extraordinary cost-increasing event occurs, as specified (or provided for) in §§ 413.182(c) and 413.188.

(e) *Criteria for retaining a previously approved exception rate.* A facility may elect to retain its previously approved exception rate in lieu of any composite rate increase or any other exception amount if—

(1) The conditions under which the exception was granted have not changed;

(2) The facility files a request to retain the rate with its fiscal intermediary during the 30-day period before the opening of an exception cycle; and

(3) The request is approved by the fiscal intermediary.

(f) *Documentation for a payment rate exception request.* If the facility is requesting an exception to its payment rate, it must submit to CMS its most recently completed cost report as required under § 413.198 and whatever statistics, data, and budgetary projections as determined by CMS to be needed to adjudicate each type of exception. CMS may audit any cost report or other information submitted. The materials submitted to CMS must—

(1) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(2) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(3) Show that the elements of excessive cost are specifically attributable to one or more conditions specified in § 413.182;

(4) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(5) Specify that the facility has compared its most recently completed cost report with cost reports from (at least 2) prior years. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request.

(g) *Completion of requirements and criteria.* The facility must demonstrate to CMS's satisfaction that the requirements of this section and the criteria in § 413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.

(h) *Approval of an exception request.* An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its intermediary.

(i) *Determination of an exception request.* In determining the facility's payment rate under the exception process, CMS excludes all costs that are not reasonable or allowable under the reasonable cost principles set forth in this part.

(j) *Period of approval: Payment exception request.* Except for exceptions approved under §§ 413.180(e), 413.180(k), 413.182(c), and 413.188, a prospective exception payment rate approved by CMS applies for the period from the date the complete exception request was filed with its intermediary until the earlier of the—

(1) Date the circumstances justifying the exception rate no longer exist; or

(2) End of the period during which the announced rate was to apply.

(k) *Period of approval: Payment exception request under §§ 413.182(c) and 413.188.* A prospective exception payment rate approved by CMS under §§ 413.182(c) and 413.188 applies from the date of the extraordinary event until the end of the period during which the prospective announced rate was to apply, unless CMS determines that another date is more appropriate. If CMS does not extend the exception period and the facility believes that it continues to require an exception to its rate, the facility must reapply in accordance with the procedures in this section.

(l) *Denial of an exception request.* CMS denies exception requests submitted

without the documentation specified in § 413.182 and the applicable regulations cited there.

(m) *Criteria for refiling a denied exception request.* A facility that has been denied an exception request during the 180 days may file another exception request if all required documentation is filed with the intermediary by the 180th day.

§ 413.182 Criteria for approval of exception requests.

CMS may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

(a) Atypical service intensity (patient mix), as specified in § 413.184.

(b) Isolated essential facility, as specified in § 413.186.

(c) Extraordinary circumstances, as specified in § 413.188.

(d) Self-dialysis training costs, as specified in § 413.190.

(e) Frequency of dialysis, as specified in § 413.192.

§ 413.184 Payment exception: Atypical service intensity (patient mix).

(a) To qualify for an exception to the prospective payment rate based on atypical service intensity (patient mix)—

(1) A facility must demonstrate that a substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients. Examples that may qualify under this criterion are more intense dialysis services that are medically necessary for patients such as—

(i) Patients who have been referred from other facilities on a temporary basis for more intense care during a period of medical instability and who return to the original facility after stabilization;

(ii) Pediatric patients who require a significantly higher staff-to-patient ratio than typical adult patients; or

(iii) Patients with medical conditions that are not commonly treated by ESRD facilities and that complicate the dialysis procedure.

(2) The facility must demonstrate clearly that these services, procedures, or supplies and its per treatment costs are prudent and reasonable when compared to those of facilities with a similar patient mix.

(3) A facility must demonstrate that—

(i) Its nursing personnel costs have been allocated properly between each mode of care; and

(ii) The additional nursing hours per treatment are not the result of an excess number of employees.

(b) *Documentation.* (1) A facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed fiscal or calendar year showing—

(i) Patients who received transplants, including the date of transplant;

(ii) Patients awaiting a transplant who are medically able, have given consent, and are on an active transplant list, and projected transplants;

(iii) Home patients;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Individual patient diagnosis;

(vi) Diabetic patients;

(vii) Patients isolated because of contagious disease;

(viii) Age of patients;

(ix) Mortality rate, by age and diagnosis;

(x) Number of patient transfers, reasons for transfers, and any related information; and

(xi) Total number of hospital admissions for the facility's patients, reason for, and length of stay of each session.

(2) The facility also must—

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed fiscal year cost report showing—

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C) That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing—

(A) The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

§ 413.186 Payment exception: Isolated essential facility.

(a) *Qualifications*. To qualify for an exception to the prospective payment rate based on being an isolated essential facility—

(1) The facility must be the only supplier of dialysis in its geographical area;

(2) The facility's patients must be unable to obtain dialysis services elsewhere without substantial additional hardship; and

(3) The facility's excess costs must be justifiable.

(b) *Criteria for determining qualifications*. In determining whether a facility qualifies for an exception based on its being an isolated essential facility, CMS considers—

(1) Local, permanent residential population density;

(2) Typical local commuting distances from medical services;

(3) Volume of treatments; and

(4) The extent that other dialysis facilities are used by area residents (other than the applying facility's patients).

(c) *Documentation*. (1) *Isolated*. Generally, to be considered isolated, the facility must document that it is located outside an established Metropolitan Statistical Area and provides dialysis to a permanent patient population, as opposed to a transient patient population.

(2) *Essential*. To be considered essential, the facility must document—

(i) That a substantial number of its patients cannot obtain dialysis services elsewhere without additional hardship; and

(ii) The additional hardship the patients will incur in travel time and cost.

(3) *Cost per treatment*. The facility must—

(i) Document that its cost per treatment is reasonable; and

(ii) Explain how the facility's cost per treatment in excess of its composite rate relates to the isolated essential facility criteria specified in paragraph (b) of this section.

(4) *Additional information*. The facility must also furnish the following information in a format that concisely explains the facility's cost and patient data to support its request:

(i) A list of current and requested payment rates for each modality.

(ii) An explanation of how the facility's costs in excess of its composite rate payment are attributable to its being an isolated essential facility.

(iii) An explanation of any unusual geographic conditions in the area surrounding the facility.

(iv) A copy of the latest filed cost report and a budget estimate for the next 12 months prepared on cost report forms.

(v) An explanation of unusual costs reported on the facility's actual or budgeted cost reports and any significant changes in budgeted costs and data compared to actual costs and data reported on the latest filed cost report.

(vi) The name, location of, and distance to the nearest renal dialysis facility.

(vii) A list of patients by modality showing commuting distance and time to the current and the next nearest renal dialysis facility.

(viii) The historical and projected patient-to-staff ratios and number of machines used for maintenance dialysis treatments.

(ix) A computation showing the facility's treatment capacity, arrived at by taking the total stations multiplied by the number of hours of operation for the year divided by the average length of a dialysis treatment.

(x) The geographic boundaries and population size of the facility's service area.

§413.188 Payment exception: Extraordinary circumstances.

(a) To qualify for an exception to the prospective payment rate based on extraordinary circumstances, the facility must substantiate that it incurs excess costs beyond its control due to a fire, earthquake, flood, or other natural disaster.

(b) CMS will not grant an exception based on increased costs if a facility has chosen not to—

(1) Maintain adequate insurance protection against such losses (through the purchase of insurance, the maintenance of a self-insurance program, or other equivalent alternative); or

(2) File a claim for losses covered by insurance or utilize its self-insurance program.

§413.190 Payment exception: Self-dialysis training costs.

(a) *Qualifications*. To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the facility must establish that it incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for such training sessions.

(b) *Justification*. To justify its exception request, a facility must—

(1) Separately identify those elements contributing to its costs in excess of the composite training rate; and

(2) Demonstrate that its per treatment costs are reasonable and allowable.

(c) *Criteria for determining proper cost reporting*. CMS considers the facility's total costs, cost finding and apportionment, including its allocation of costs, to determine if costs are properly reported by treatment modality.

(d) *Limitation of exception requests*. Exception requests for a higher training rate are limited to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.

(e) *Documentation*. The facility must provide the following information to support its exception request:

(1) A copy of the facility's training program.

(2) Computation of the facility's cost per treatment for maintenance sessions and training sessions including an explanation of the cost difference between the two modalities.

(3) Class size and patients' training schedules.

(4) Number of training sessions required, by treatment modality, to train patients.

(5) Number of patients trained for the current year and the prior 2 years on a monthly basis.

(6) Projection for the next 12 months of future training candidates.

(7) The number and qualifications of staff at training sessions.

(f) *Accelerated training exception*. (1) An ESRD facility may bill Medicare for a dialysis training session only when a patient receives a dialysis treatment (normally three times a week for hemodialysis). Continuous cycling peritoneal dialysis (CCPD) and continuous ambulatory peritoneal dialysis (CAPD) are daily treatment modalities; ESRD facilities are paid the equivalent of three hemodialysis treatments for each week that CCPD and CAPD treatments are provided.

(2) If an ESRD facility elects to train all its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of billable training dialysis sessions is less than the number of actual training sessions, the facility may request a composite rate exception, limited to the lesser of the—

(i) Facility's projected training cost per treatment; or

(ii) Cost per treatment the facility would have received in training a patient if it had trained patients only during a dialysis treatment, that is, three times per week.

(3) An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD training.

(4) In computing the payment amount under an accelerated training exception, CMS uses a minimum number of training sessions per patient (15 for hemodialysis and 5 for CAPD and CCPD) when the facility actually provides fewer than the minimum number of training sessions.

(5) To justify an accelerated training exception request, an ESRD facility must document that a significant number of training sessions for a particular modality are provided during a shorter but more condensed period.

(6) The facility must submit with the exception request a list of patients, by modality, trained during the most recent cost report period. The list must include each beneficiary's—

(i) Name;

(ii) Age; and

(iii) Training status (completed, not completed, being retrained, or in the process of being trained).

(7) The total treatments from the patient list must be the same as the total treatments reported on the cost report filed with the request.

§ 413.192 Payment exception: Frequency of dialysis.

(a) *Qualification*. To qualify for an exception to the prospective payment rate based on frequency of dialysis, the facility must establish that it has a substantial portion of outpatient maintenance dialysis treatments furnished to patients who dialyze less frequently than three times per week.

(b) *Definition*. For purposes of this section, ''substantial'' means the number of treatments furnished by the facility is at least 15 percent lower than the number would be if all patients dialyzed three times a week.

(c) *Limitation for per treatment payment rates*. Per treatment payment rates granted under this exception may not exceed the amount that produces weekly payments per patient equal to three times the facility's prospective composite rate, exclusive of any exception amounts.

(d) *Documentation*. To document that an ESRD facility furnishes a substantial number of dialysis treatments at a frequency less than three times per week per patient, the facility must submit the following information:

(1) A list of patients receiving outpatient dialysis treatments for the cost report that is filed with the request. The list must indicate—

(i) Whether the patients are permanent, transient, or temporary;

(ii) The medically prescribed frequency of dialysis; and

(iii) The number of dialysis treatments that each patient received on a weekly and yearly basis and an explanation of any discrepancy between that calculation and the number of treatments reported on the facility's cost report.

(2) A list of patients used to project treatments. The list must indicate—

(i) Whether the patients are permanent, transient, or temporary;

(ii) The medically prescribed frequency of dialysis;

(iii) The number of dialysis treatments that each patient is projected to receive on a weekly and yearly basis, an explanation of any discrepancy between that calculation and the number of treatments reported on the facility's projected cost report, and an explanation for any change among prior, actual, and projected data.

(3) A schedule showing the number of treatments to be furnished twice a week and the number of treatments that would have been furnished if each patient were dialyzed three times a week.

(4) A computation of the facility's projected costs per treatment using the—

(i) Projected number of treatments furnished twice a week; and

(ii) Number of treatments if patients dialyze three times a week.

(5) A schedule showing the computation of the percentage decrease in the number of treatments.

§ 413.194 Appeals.

(a) *Appeals under section 1878 of the Act*. (1) A facility that disputes the amount of its allowable Medicare bad debts reimbursed by CMS under § 413.178 may request review by the

intermediary or the Provider Reimbursement Review Board (PRRB) in accordance with subpart R of part 405 of this chapter.

(2) A facility must request and obtain a final agency decision prior to seeking judicial review of a dispute regarding the amount of allowable Medicare bad debts.

(b) *Other appeals.* (1) A facility that has requested higher payment per treatment in accordance with §413.180 may request review from the intermediary or the PRRB if CMS has denied the request in whole or in part. In such a case, the procedure in subpart R of part 405 of this chapter is followed to the extent that it is applicable.

(2) The PRRB has the authority to review the action taken by CMS on the facility's requests. However, the PRRB's decision is subject to review by the Administrator under §405.1875 of this chapter.

(3) A facility must request and obtain a final agency decision, in accordance with paragraph (b)(1) of this section, prior to seeking judicial review of the denial, in whole or in part, of the exception request.

(c) *Procedure.* (1) The facility must request review within 180 days of the date of the decision on which review is sought.

(2) The facility may not submit to the reviewing entity, whether it is the intermediary or the PRRB, any additional information or cost data that had not been submitted to CMS at the time CMS evaluated the exception request.

(d) *Determining amount in controversy.* For purposes of determining PRRB jurisdiction under subpart R of part 405 of this chapter for the appeals described in paragraph (b) of this section—

(1) The amount in controversy per treatment is determined by subtracting the amount of program payment from the amount the facility requested under §413.180; and

(2) The total amount in controversy is calculated by multiplying the amount in controversy per treatment by the projected number of treatments for the exception request period.

§413.196 Notification of changes in rate-setting methodologies and payment rates.

(a) CMS or the facility's intermediary notifies each facility of changes in its payment rate. This notice includes changes in individual facility payment rates resulting from corrections or revisions of particular geographic labor cost adjustment factors.

(b) Changes in payment rates resulting from incorporation of updated cost data or general revisions of geographic labor cost adjustment factors are announced by notice published in the FEDERAL REGISTER without opportunity for prior comment. Revisions of the rate-setting methodology are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

§413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and Scope.* This section implements section 1881(b)(2)(B)(i) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities approved under subpart U of part 405 of this chapter. The records and reports will enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in §413.170(a).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate CMS-approved cost report in accordance with §§413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively.

(2) The cost reimbursement principles set forth in this part (beginning with §413.134, Depreciation, and excluding the principles listed in paragraph (b)(4) of this section), apply in the determination and reporting of the allowable cost incurred in furnishing outpatient maintenance dialysis treatments to patients dialyzing in the facility, or incurred by the facility in furnishing home dialysis service, supplies, and equipment.

(3) Allowable cost is the reasonable cost related to dialysis treatments. Reasonable cost includes all necessary

and proper expenses incurred by the facility in furnishing the dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. Reasonable cost does not include costs that—

(i) Are not related to patient care for outpatient maintenance dialysis;

(ii) Are for services or items specifically not reimbursable under the program;

(iii) Flow from the provision of luxury items or servicess (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

(iv) Are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(4) The following principles of this part do not apply in determining adjustments to allowable costs as reported by ESRD facilities:

(i) Section 413.157, Return on equity capital of proprietary providers;

(ii) Section 413.200, Reimbursement of OPAs and histocompatibility laboratories;

(iii) Section 413.9, Cost related to patient care (except for the principles stated in paragraph (b)(3) of this section); and

(iv) Sections 413.64, Payments to providers, and §§ 413.13, 413.30, 413.35, 413.40, 413.74, and §§ 415.55 through 415.70, § 415.162, and § 415.164 of this chapter, Principles of reimbursement for services by hospital-based physicians.

§ 413.200 Payment of independent organ procurement organizations and histocompatibility laboratories.

(a) *Principle.* Covered services furnished after September 30, 1978 by organ procurement organizations (OPOs) and histocompatibility laboratories in connection with kidney acquisition and transplantation will be reimbursed under the principles for determining reasonable cost contained in this part. Services furnished by freestanding OPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, will be reimbursed by making an interim payment to the transplant hospitals using these services and by making a retroactive adjustment, directly with the OPO or laboratory, based upon a cost report filed by the OPO or laboratory. (The reasonable costs of services furnished by hospital based OPOs or laboratories will be reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* For purposes of this section:

Freestanding refers to an OPO or a histocompatibility laboratory that is not—

(1) Subject to the control of the hospital with respect to the hiring, firing, training, and paying of employees; and

(2) Considered as a department of the hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

Histocompatibility laboratory means a laboratory meeting the standards and providing the services for kidneys or other organs set forth in § 413.2171(d) of this chapter.

OPO means an organization defined in § 486.302 of this chapter.

(c) *Agreements with independent OPOs and laboratories.* (1) Any freestanding OPO or histocompatibility laboratory that wishes to have the cost of its pretransplant services reimbursed under the Medicare program must file an agreement with CMS under which the OPO or laboratory agrees—

(i) To file a cost report in accordance with § 413.24(f) within three months after the end of each fiscal year;

(ii) To permit CMS to designate an intermediary to determine the interim reimbursement rate payable to the transplant hospitals for services provided by the OPO or laboratory and to make a determination of reasonable cost based upon the cost report filed by the OPO or laboratory;

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;

(iv) To pay to CMS amounts that have been paid by CMS to transplant

hospitals and that are determined to be in excess of the reasonable cost of the services provided by the OPO or laboratory; and

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1861 of the Act.

(2) The initial cost report due from an OPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c) (1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) *Interim reimbursement.* (1) Hospitals eligible to receive Medicare reimbursement for renal transplantation will be paid for the pretransplantation services of a freestanding OPO or histocompatibility laboratory that has an agreement with the Secretary under paragraph (c) of this section, on the basis of an interim rate established by an intermediary for that OPO or laboratory.

(2) The interim rate will be based on the average cost per service incurred by an OPO or laboratory, during its previous fiscal year, associated with procuring a kidney for transplantation. This interim rate may be adjusted if necessary for anticipated cost changes. If there is not adequate cost data to determine the initial interim rate, it will be determined according to the OPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made on the basis of the interim rate will be reconciled directly with the OPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all freestanding OPOs and histocompatibility laboratories shall be disseminated to all transplant hospitals and intermediaries.

(e) *Retroactive adjustment.* (1) *Cost reports.* Information provided in cost reports by freestanding OPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in paragraphs (a) through (e) of § 413.24. These cost reports must provide a complete accounting of the cost incurred by the agency or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services, and any other data necessary to enable the intermediary to make a determination of the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by a freestanding OPO or histocompatibility laboratory will be reviewed by the intermediary and a new interim reimbursement rate for the succeeding fiscal year will be established based upon this review. A retroactive adjustment in the amount paid under the interim rate will be made in accordance with § 413.64(f). If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to transplant hospitals, a lump sum adjustment will be made directly between that intermediary and the OPO or laboratory.

(f) For services furnished on or after April 1, 1988, no payment may be made for services furnished by an OPO that does not meet the requirements of part 485, subpart D of this chapter.

(g) *Appeals.* Any OPO or histocompatibility laboratory that disagrees with an intermediary's cost determination under this section is entitled to an intermediary hearing, in accordance with the procedures contained in §§ 405.1811 through 405.1833, if the amount in controversy is $1,000 or more.

§ 413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

An OPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. OPOs, as defined in § 435.302 of this chapter, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal intermediaries. Medicare costs are based on

the ratio of the number of usable kidneys transplanted into Medicare beneficiaries to the total number of usable kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes. The OPO must submit a request to the fiscal intermediary for review and approval of these arrangements.

§ 413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

(a) A transplant center's total costs for all organs is reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. Organs are defined in § 486.302 (only covered organs will be paid for on a reasonable cost basis).

(b) Transplant center hospitals must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare fiscal intermediaries.

(c) Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs applied to reasonable costs.

Subpart I—Prospectively Determined Payment Rates for Low-Volume Skilled Nursing Facilities, for Cost Reporting Periods Beginning Prior to July 1, 1998

SOURCE: 60 FR 37594, July 21, 1995, unless otherwise noted.

§ 413.300 Basis and scope.

(a) *Basis*. This subpart implements section 1888(d) of the Act, which provides for optional prospectively determined payment rates for qualified SNFs.

(b) *Scope*. This subpart sets forth the eligibility criteria an SNF must meet to qualify, the process governing election of prospectively determined payment rates, and the basis and methodology for determining prospectively determined payment rates.

§ 413.302 Definitions.

For purposes of this subpart—

Area wage level means the average wage per hour for all classifications of employees as reported by health care facilities within a specified area.

Census region means one of the 9 census divisions, comprising the 50 States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes.

Routine capital-related costs means the capital-related costs, allowable for Medicare purposes (as described in Subpart G of this Part), that are allocated to the SNF participating inpatient routine service cost center as reported on the Medicare cost report.

Routine operating costs means the cost of regular room, dietary, and nursing services, and minor medical and surgical supplies for which a separate charge is not customarily made. It does not include the costs of ancillary services, capital-related costs, or, where appropriate, return on equity.

Rural area means any area outside an urban area in a census region.

Urban area means—

(1) Prior to October 1, 2004, a Metropolitan Statistical Area (MSA), or New England County Metropolitan Area (NECMA), as defined by the Office of Management and Budget, or a New England county deemed to be an urban area as listed in § 412.62(f)(1)(ii)(B) of this chapter.

(2) Effective October 1, 2004, a Metropolitan Statistical Area (MSA), as defined by the Office of Management and Budget, or a New England county deemed to be an urban area as specified under § 412.64.

[60 FR 37594, July 21, 1995, as amended at 69 FR 49265, Aug. 11, 2004]

§ 413.304 Eligibility for prospectively determined payment rates.

(a) *General rule*. An SNF is eligible to receive a prospectively determined

payment rate for a cost reporting period if it had fewer than 1,500 Medicare covered inpatient days as reported on a Medicare cost report in its immediately preceding cost reporting period. This criterion applies even if the SNF received a prospectively determined payment rate during the preceding cost reporting period.

(b) *Less than a full cost reporting period.* If the cost reporting period that precedes an SNF's request for prospectively determined payment is not a full cost reporting period, the SNF is eligible to receive prospectively determined payment rates only if the average daily Medicare census for the period (Medicare inpatient days divided by the total number of days in the cost reporting period) is not greater than 4.1.

(c) *Newly-participating SNFs.* An SNF is eligible to receive prospectively determined payment rates for its first cost reporting period for which it is approved to participate in Medicare.

§413.308 Rules governing election of prospectively determined payment rates.

(a) *Requirements.* An SNF must notify its intermediary at least 30 calendar days before the beginning of the cost reporting period for which it requests to receive such payment that it elects prospectively determined payment rates. A separate request must be made for each cost reporting period for which an SNF seeks prospectively determined payment. A newly participating SNF with no preceding cost reporting period must make its election within 30 days of its notification of approval to participate in Medicare.

(b) *Intermediary notice.* After evaluating an SNF's request for prospectively determined payment rates, the intermediary notifies the SNF in writing as to whether the SNF meets any of the eligibility criteria described in §413.304 and the timely election requirements under §413.308(a). The intermediary must notify the SNF of its initial and final determinations within 10 working days after it receives all the data necessary to make each determination. The intermediary's determination is limited to one cost reporting period.

(c) *Prohibition against revocation.* An SNF may not revoke its request after it has received the initial determination of eligibility from the intermediary and the cost reporting period has begun.

(d) *Revocation by intermediary.* If an SNF is given tentative approval to receive a prospectively determined payment rate, and, after the start of the applicable cost reporting period, the intermediary determines that the SNF does not meet the eligibility criteria, the intermediary must revoke the prospectively determined payment option.

§413.310 Basis of payment.

(a) *Method of payment.* Under the prospectively determined payment rate system, a qualified SNF receives a per diem payment of a predetermined rate for inpatient services furnished to Medicare beneficiaries. Each SNF's routine per diem payment rate is determined according to the methodology described in §413.312 and is based on various components of SNF costs.

(b) *Payment in full.* The payment rate represents payment in full for routine services as described in §413.314 (subject to applicable coinsurance as described in Subpart G of Part 409 of this title), and for routine capital costs. Payment is made in lieu of payment on a reasonable cost basis for routine services and for routine capital costs.

§413.312 Methodology for calculating rates.

(a) *Data used.* (1) To calculate the prospectively determined payment rates, CMS uses:

(i) The SNF cost data that were used to develop the applicable routine service cost limits;

(ii) A wage index to adjust for area wage differences; and

(iii) The most recent projections of increases in the costs from the SNF market basket index.

(2) In the annual schedule of rates published in the FEDERAL REGISTER under the authority of §413.320, CMS announces the wage index and the annual percentage increases in the market basket used in the calculation of the rates.

(b) *Calculation of per diem rate.* (1) *Routine operating component of rate*—(i)

Adjusting cost report data. The SNF market basket index is used to adjust the routine operating cost from the SNF cost report to reflect cost increases occurring between cost reporting periods represented in the data collected and the midpoint of the initial cost reporting period to which the payment rates apply.

(ii) *Calculating a per diem cost.* For each SNF, an adjusted routine operating per diem cost is computed by dividing the adjusted routine operating cost (see paragraph (b)(1)(i) of this section) by the SNF's total patient days.

(iii) *Adjusting for wage levels.* (A) The SNF's adjusted per diem routine operating cost calculated under paragraph (b)(1)(ii) of this section is then divided into labor-related and nonlabor-related portions.

(B) The labor-related portion is obtained by multiplying the SNF's adjusted per diem routine operating cost by a percentage that represents the labor-related portion of cost from the market basket. This percentage is published when the revised rates are published as described in § 413.320.

(C) The labor-related portion of each SNF's per diem cost is divided by the wage index applicable to the SNF's geographic location to arrive at the adjusted labor-related portion of routine cost.

(iv) *Group means.* SNFs are grouped by urban or rural location by census region. Separate means of adjusted labor-related and nonlabor routine operating costs for each SNF group are established in accordance with the SNF's region and urban or rural location. For each group, the mean labor-related and mean nonlabor-related per diem routine operating costs are multiplied by 105 percent.

(2) *Computation of routine capital-related cost.*

(i) The SNF routine capital-related cost for both direct and indirect capital costs allocated to routine services, as reported on the Medicare cost report, is obtained for each SNF in the data base.

(ii) For each SNF, the per diem capital-related cost is calculated by dividing the SNF's routine capital costs by its inpatient days.

(iii) SNFs are grouped by urban and rural location by census region, and mean per diem routine capital-related cost is determined for each group.

(iv) Each group mean per diem capital-related cost is multiplied by 105 percent.

(3) *Computation of return on owner's equity for services furnished before October 1, 1993.* (i) Each proprietary SNF's Medicare return on equity is obtained from its cost report and the portion attributable to the routine service cost is determined as described in § 413.157.

(ii) For each proprietary SNF, per diem return on equity is calculated by dividing the routine cost related return on equity determined under paragraph (b)(3)(i) of this section by the SNF's total Medicare inpatient days.

(iii) Separate group means are computed for per diem return on equity of proprietary SNFs, based on regional and urban or rural classification.

(iv) Each group mean is multiplied by 105 percent.

§ 413.314 Determining payment amounts: Routine per diem rate.

(a) *General rule.* An SNF that elects to be paid under the prospectively determined payment rate system, and qualifies for such payment, is paid a per diem rate for inpatient routine services. This rate is adjusted to reflect area wage differences and the cost reporting period beginning date (if necessary) and is subject to the limitation specified in paragraph (d) of this section.

(b) *Per diem rate.* The prospectively determined payment rate for each urban and rural area in each census region is comprised of the following:

(1) A routine operating component, which is divided into:

(i) A labor-related portion adjusted by the appropriate wage index; and

(ii) A nonlabor-related portion.

(2) A routine capital-related cost portion.

(3) For proprietary SNFs only, a portion that is based on the return on owner's equity related to routine cost, applicable only for services furnished before October 1, 1993.

(c) *Adjustment for cost reporting period.* (1) If a facility has a cost reporting period beginning after the beginning of the Federal fiscal year, the intermediary increases the labor-related

and nonlabor-related portions of the prospective payment rate that would otherwise apply to the SNF by an adjustment factor. Each factor represents the projected increase in the market basket index for a specific 12-month period. The factors are used to account for inflation in costs for cost reporting periods beginning after October 1. Adjustment factors are published in the annual notice of prospectively determined payment rates described in § 413.320.

(2) If a facility uses a cost reporting period that is not 12 months in duration, the intermediary must obtain a special adjustment factor from CMS for the specific period.

(d) *Limitation of prospectively determined payment rate.* The per diem prospectively determined payment rate for an SNF, excluding capital-related costs and excluding return on equity for services furnished prior to October 1, 1993, may not exceed the individual SNF's routine service cost limit. Under § 413.30, the routine service cost limit is the limit determined without regard to exemptions, exceptions, or retroactive adjustments, and is the actual limit in effect when the provider elects to be paid a prospectively determined payment rate.

§ 413.316 Determining payment amounts: Ancillary services.

Ancillary services are paid on the basis of reasonable cost in accordance with section 1861(v)(1) of the Act and § 413.53.

§ 413.320 Publication of prospectively determined payment rates or amounts.

At least 90 days before the beginning of a Federal fiscal year to which revised prospectively determined payment rates are to be applied, CMS publishes a notice in the FEDERAL REGISTER:

(a) Establishing the prospectively determined payment rates for routine services; and

(b) Explaining the basis on which the prospectively determined payment rates are calculated.

§ 413.321 Simplified cost report for SNFs.

SNFs electing to be paid under the prospectively determined payment rate system may file a simplified cost report. The cost report contains a simplified method of cost finding to be used in lieu of cost methods described in § 413.24(d). This method is specified in the instructions for Form CMS–2540S, contained in sections 3000–3027.3 of Part 2 of the Provider Reimbursement Manual. This form may not be used by hospital-based SNFs or SNFs that are part of a health care complex. Those SNFs must file a cost report that reflects the shared services and administrative costs of the hospital and any other related facilities in the health care complex.

Subpart J—Prospective Payment for Skilled Nursing Facilities

SOURCE: 63 FR 26309, May 12, 1998, unless otherwise noted.

§ 413.330 Basis and scope.

(a) *Basis.* This subpart implements section 1888(e) of the Act, which provides for the implementation of a prospective payment system for SNFs for cost reporting periods beginning on or after July 1, 1998.

(b) *Scope.* This subpart sets forth the framework for the prospective payment system for SNFs, including the methodology used for the development of payment rates and associated adjustments, the application of a transition phase, and related rules.

§ 413.333 Definitions.

As used in this subpart—

Case-mix index means a scale that measures the relative difference in resource intensity among different groups in the resident classification system.

Market basket index means an index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered skilled nursing services.

Resident classification system means a system for classifying SNF residents into mutually exclusive groups based on clinical, functional, and resource-

based criteria. For purposes of this subpart, this term refers to the current version of the Resource Utilization Groups, as set forth in the annual publication of Federal prospective payment rates described in § 413.345.

Rural area means any area outside of an urban area.

Urban area means a metropolitan statistical area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Office of Management and Budget, or a New England county deemed to be an urban area, as listed in § 412.62(f)(1)(ii)(B) of this chapter.

[63 FR 26309, May 12, 1998; 63 FR 53307, Oct. 5, 1998]

§ 413.335 Basis of payment.

(a) *Method of payment.* Under the prospective payment system, SNFs receive a per diem payment of a predetermined rate for inpatient services furnished to Medicare beneficiaries. The per diem payments are made on the basis of the Federal payment rate described in § 413.337 and, during a transition period, on the basis of a blend of the Federal rate and the facility-specific rate described in § 413.340. These per diem payment rates are determined according to the methodology described in § 413.337 and § 413.340.

(b) *Payment in full.* The payment rates represent payment in full (subject to applicable coinsurance as described in subpart G of part 409 of this chapter) for all costs (routine, ancillary, and capital-related) associated with furnishing inpatient SNF services to Medicare beneficiaries other than costs associated with operating approved educational activities as described in § 413.85.

§ 413.337 Methodology for calculating the prospective payment rates.

(a) *Data used.* (1) To calculate the prospective payment rates, CMS uses—

(i) Medicare data on allowable costs from freestanding and hospital-based SNFs for cost reporting periods beginning in fiscal year 1995. SNFs that received ''new provider'' exemptions under § 413.30(e)(2) are excluded from the data base used to compute the Federal payment rates. In addition, allowable costs related to exceptions payments under § 413.30(f) are excluded from the data base used to compute the Federal payment rates;

(ii) An appropriate wage index to adjust for area wage differences;

(iii) The most recent projections of increases in the costs from the SNF market basket index;

(iv) Resident assessment and other data that account for the relative resource utilization of different resident types; and

(v) Medicare Part B SNF claims data reflecting amounts payable under Part B for covered SNF services (other than those services described in § 411.15(p)(2) of this chapter) furnished during SNF cost reporting periods beginning in fiscal year 1995 to individuals who were residents of SNFs and receiving Part A covered services.

(b) *Methodology for calculating the per diem Federal payment rates*—(1) *Determining SNF costs.* In calculating the initial unadjusted Federal rates applicable for services provided during the period beginning July 1, 1998 through September 30, 1999, CMS determines each SNF's costs by summing its allowable costs for the cost reporting period beginning in fiscal year 1995 and its estimate of Part B payments (described in paragraphs (a)(1)(i) and (a)(1)(v) of this section).

(2) *Use of market basket index.* The SNF market basket index is used to adjust the SNF cost data to reflect cost increases occurring between cost reporting periods represented in the data and the initial period (beginning July 1, 1998 and ending September 30, 1999) to which the payment rates apply. For each year, the cost data are updated by a factor equivalent to the annual market basket index percentage minus 1 percentage point.

(3) *Calculation of the per diem cost.* For each SNF, the per diem cost is computed by dividing the cost data for each SNF by the corresponding number of Medicare days.

(4) *Standardization of data for variation in area wage levels and case-mix.* The cost data described in paragraph (b)(2) of this section are standardized to remove the effects of geographic variation in wage levels and facility variation in case-mix. The cost data are standardized for geographic variation in wage levels using the wage

index. The cost data are standardized for facility variation in case-mix using the case-mix indices and other data that indicate facility case-mix.

(5) *Calculation of unadjusted Federal payment rates.* CMS calculates the national per diem unadjusted payment rates by urban and rural classification in the following manner:

(i) By computing the average per diem standardized cost of freestanding SNFs weighted by Medicare days.

(ii) By computing the average per diem standardized cost of freestanding and hospital-based SNFs combined weighted by Medicare days.

(iii) By computing the average of the amounts determined under paragraphs (b)(5)(i) and (b)(5)(ii) of this section.

(c) *Calculation of adjusted Federal payment rates for case-mix and area wage levels.* The Federal rate is adjusted to account for facility case-mix using a resident classification system and associated case-mix indices that account for the relative resource utilization of different patient types. This classification system utilizes the resident assessment instrument completed by SNFs as described at §483.20 of this chapter, according to the assessment schedule described in §413.343(b). The Federal rate is also adjusted to account for geographic differences in area wage levels using an appropriate wage index.

(d) *Annual updates of Federal unadjusted payment rates.* CMS updates the unadjusted Federal payment rates on a fiscal year basis.

(1) For fiscal years 2000 through 2002, the unadjusted Federal rate is equal to the rate for the previous period or fiscal year increased by a factor equal to the SNF market basket index percentage minus 1 percentage point.

(2) For subsequent fiscal years, the unadjusted Federal rate is equal to the rate for the previous fiscal year increased by the applicable SNF market basket index amount. Beginning with fiscal year 2004, an adjustment to the annual update of the previous fiscal year's rate will be computed to account for forecast error. The initial adjustment (in fiscal year 2004) to the update of the previous fiscal year's rate will take into account the cumulative forecast error between fiscal years 2000 and 2002. Subsequent adjustments in succeeding fiscal years will take into account the forecast error from the most recently available fiscal year for which there is final data.

(e) Pursuant to section 101 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) as revised by section 314 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), using the best available data, the Secretary will issue a new regulation with a newly refined case-mix classification system to better account for medically complex patients. Upon issuance of the new regulation, the temporary increases in payment for certain high cost patients will no longer be applicable.

[63 FR 26309, May 12, 1998, as amended at 66 FR 39600, July 31, 2001; 68 FR 46070, Aug. 4, 2003]

§413.340 Transition period.

(a) *Duration of transition period and proportions for the blended transition rate.* Beginning with an SNF's first cost reporting period beginning on or after July 1, 1998, there is a transition period covering three cost reporting periods. During this transition phase, SNFs receive a payment rate comprising a blend of the adjusted Federal rate and a facility-specific rate. For the first cost reporting period beginning on or after July 1, 1998, payment is based on 75 percent of the facility-specific rate and 25 percent of the Federal rate. For the subsequent cost reporting period, the rate is comprised of 50 percent of the facility-specific rate and 50 percent of the Federal rate. In the final cost reporting period of the transition, the rate is comprised of 25 percent of the facility-specific rate and 75 percent of the Federal rate. For all subsequent cost reporting periods, payment is based entirely on the Federal rate.

(b) *Calculation of facility-specific rate for the first cost reporting period.* The facility-specific rate is computed based on the SNF's Medicare allowable costs from its fiscal year 1995 cost report plus an estimate of the amounts payable under Part B for covered SNF services (other than those services described in §411.15(p)(2) of this chapter) furnished during fiscal year 1995 to individuals who were residents of SNFs

and receiving Part A covered services. Allowable costs associated with exceptions, as described in § 413.30(f), are included in the calculation of the facility-specific rate. Allowable costs associated with exemptions, as described in § 413.30(e)(2), are included in the calculation of the facility-specific rate but only to the extent that they do not exceed 150 percent of the routine cost limit. Low Medicare volume SNFs that were paid a prospectively determined rate under § 413.300 for their cost reporting period beginning in fiscal year 1995 will utilize that rate as the basis for the allowable costs of routine (operating and capital-related) expenses in determining the facility-specific rate. Each SNF's allowable costs are updated to the first cost reporting period to which the payment rates apply using annual factors equal to the SNF market basket percentage minus 1 percentage point.

(c) *SNFs participating in the Multistate Nursing Home Case-Mix and Quality Demonstration.* SNFs that participated in the Multistate Nursing Home Case-Mix and Quality Demonstration in a cost reporting period that began in calendar year 1997 will utilize their allowable costs from that cost reporting period, including prospective payment amounts determined under the demonstration payment methodology.

(d) *Update of facility-specific rates for subsequent cost reporting periods.* The facility-specific rate for a cost reporting period that is subsequent to the first cost reporting period is equal to the facility-specific rate for the first cost reporting period (described in paragraph (a) of this section) updated by the market basket index.

(1) For a subsequent cost reporting period beginning in fiscal years 1998 and 1999, the facility-specific rate is equal to the facility-specific rate for the previous cost reporting period updated by the applicable market basket index percentage minus one percentage point.

(2) For a subsequent cost reporting period beginning in fiscal year 2000, the facility-specific rate is equal to the facility-specific rate for the previous cost reporting period updated by the applicable market basket index percentage.

(e) *SNFs excluded from the transition period.* SNFs that received their first payment from Medicare, under present or previous ownership, on or after October 1, 1995, are excluded from the transition period, and payment is made according to the Federal rates only.

§ 413.343 Resident assessment data.

(a) *Submission of resident assessment data.* SNFs are required to submit the resident assessment data described at § 483.20 of this chapter in the manner necessary to administer the payment rate methodology described in § 413.337. This provision includes the frequency, scope, and number of assessments required.

(b) *Assessment schedule.* In accordance with the methodology described in § 413.337(c) related to the adjustment of the Federal rates for case-mix, SNFs must submit assessments according to an assessment schedule. This schedule must include performance of patient assessments on the 5th, 14th, 30th, 60th, and 90th days of posthospital SNF care and such other assessments that are necessary to account for changes in patient care needs.

(c) *Noncompliance with assessment schedule.* CMS pays a default rate for the Federal rate when a SNF fails to comply with the assessment schedule in paragraph (b) of this section. The default rate is paid for the days of a patient's care for which the SNF is not in compliance with the assessment schedule.

[63 FR 26309, May 12, 1998, as amended at 64 FR 41682, July 30, 1999]

§ 413.345 Publication of Federal prospective payment rates.

CMS publishes information pertaining to each update of the Federal payment rates in the FEDERAL REGISTER. This information includes the standardized Federal rates, the resident classification system that provides the basis for case-mix adjustment (including the designation of those specific Resource Utilization Groups under the resident classification system that represent the required SNF level of care, as provided in § 409.30 of this chapter), and the wage index. This information is published before May 1 for the

fiscal year 1998 and before August 1 for the fiscal years 1999 and after.

[60 FR 37594, July 21, 1995, as amended at 68 FR 46071, Aug. 4, 2003]

§ 413.348 Limitation on review.

Judicial or administrative review under sections 1869 or 1878 of the Act or otherwise is prohibited with regard to the establishment of the Federal rates. This prohibition includes the methodology used in the computation of the Federal standardized payment rates, the case-mix methodology, and the development and application of the wage index. This prohibition on judicial and administrative review also extends to the methodology used to establish the facility-specific rates but not to determinations related to reasonable cost in the fiscal year 1995 cost reporting period used as the basis for these rates.

§ 413.350 Periodic interim payments for skilled nursing facilities receiving payment under the skilled nursing facility prospective payment system for Part A services.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, SNFs receiving payment under the PPS for Part A services do not receive interim payments during the cost reporting year, and receive payment only following submission of a bill. Paragraph (d) of this section provides for accelerated payments in certain circumstances.

(b) *Periodic interim payments.* (1) An SNF receiving payment under the prospective payment system may receive periodic interim payments (PIP) for Part A SNF services under the PIP method subject to the provisions of § 413.64(h). To be approved for PIP, the SNF must meet the qualifying requirements in § 413.64(h)(3). Moreover, as provided in § 413.64(h)(5), intermediary approval is conditioned upon the intermediary's best judgment as to whether payment can be made under the PIP method without undue risk of its resulting in an overpayment to the provider.

(2) *Frequency of payment.* The intermediary estimates an SNF's prospective payments net of estimated beneficiary coinsurance and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. If an SNF has payment experience under the prospective payment system, the intermediary estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6). The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an SNF receives interim payments for less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP*—(i) *Request by the SNF.* An SNF receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates PIP if the SNF no longer meets the requirements of § 413.64(h).

(c) *Interim payments for Medicare bad debts and for Part A costs not paid under the prospective payment system.* For Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system, the intermediary determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to 1/26 of the total estimated amount. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6). The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an SNF receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Accelerated payments*—(1) *General rule.* Upon request, an accelerated payment may be made to an SNF that is

receiving payment under the prospective payment system and is not receiving PIP under paragraph (b) of this section if the SNF is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the SNF.

(ii) Due to an exceptional situation, there is a temporary delay in the SNF's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* An SNF's request for an accelerated payment must be approved by the intermediary and CMS.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as SNF bills are processed or by direct payment by the SNF.

[64 FR 41682, July 30, 1999]

§ 413.355 Additional payment: QIO photocopy and mailing costs.

An additional payment is made to a skilled nursing facility in accordance with § 476.78 of this chapter for the costs of photocopying and mailing medical records requested by a QIO.

[68 FR 67960, Dec. 5, 2003]

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

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AUTHORITY: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

SOURCE: 55 FR 23441, June 8, 1990, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 414 appear at 60 FR 50442, Sept. 29, 1995, and 60 FR 53877, Oct. 18, 1995.

Subpart A—General Provisions

§414.1 Basis and scope.

This part implements the following provisions of the Act:

1802—Rules for private contracts by Medicare beneficiaries.

1833—Rules for payment for most Part B services.

1834(a) and (h)—Amounts and frequency of payments for durable medical equipment and for prosthetic devices and orthotics and prosthetics.

1834(l)—Establishment of a fee schedule for ambulance services.

1834(m)—Rules for Medicare reimbursement for telehealth services.

1842(o)—Rules for payment of certain drugs and biologicals.

1848—Fee schedule for physician services.

1881(b)—Rules for payment for services to ESRD beneficiaries.

1887—Payment of charges for physician services to patients in providers.

[67 FR 9132, Feb. 27, 2002, as amended at 69 FR 1116, Jan. 7, 2004]

§414.2 Definitions.

As used in this part, unless the context indicates otherwise—

AA stands for anesthesiologist assistant.

AHPB stands for adjusted historical payment basis.

CF stands for conversion factor.

CRNA stands for certified registered nurse anesthetist.

CY stands for calendar year.

FY stands for fiscal year.

GAF stands for geographic adjustment factor.

GPCI stands for geographic practice cost index.

HCPCS stands for CMS Common Procedure Coding System.

Physician services means the following services to the extent that they are covered by Medicare:

(1) Professional services of doctors of medicine and osteopathy (including osteopathic practitioners), doctors of optometry, doctors of podiatry, doctors of dental surgery and dental medicine, and chiropractors.

(2) Supplies and services covered ''incident to'' physician services (excluding drugs as specified in § 414.36).

(3) Outpatient physical and occupational therapy services if furnished by a person or an entity that is not a Medicare provider of services as defined in § 400.202 of this chapter.

(4) Diagnostic x-ray tests and other diagnostic tests (excluding diagnostic laboratory tests paid under the fee schedule established under section 1833(h) of the Act).

(5) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.

(6) Antigens, as described in section 1861(s)(2)(G) of the Act.

(7) Bone mass measurement.

RVU stands for relative value unit.

(8) Screening mammography services.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 58 FR 63686, Dec. 2, 1993; 59 FR 63463, Dec. 8, 1994; 60 FR 63177, Dec. 8, 1995; 63 FR 34328, June 24, 1998; 66 FR 55322, Nov. 1, 2001]

§ 414.4 Fee schedule areas.

(a) *General*. CMS establishes physician fee schedule areas that generally conform to the geographic localities in existence before January 1, 1992.

(b) *Changes*. CMS announces proposed changes to fee schedule areas in the FEDERAL REGISTER and provides an opportunity for public comment. After considering public comments, CMS publishes the final changes in the FEDERAL REGISTER.

[59 FR 63463, Dec. 8, 1994]

Subpart B—Physicians and Other Practitioners

SOURCE: 56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, unless otherwise noted.

§ 414.20 Formula for computing fee schedule amounts.

(a) *Participating supplier*. The fee schedule amount for a participating supplier for a physician service as defined in § 414.2 is computed as the product of the following amounts:

(1) The RVUs for the service.

(2) The GAF for the fee schedule area.

(3) The CF.

(b) *Nonparticipating supplier*. The fee schedule amount for a nonparticipating supplier for a physician service as defined in § 414.2 is 95 percent of the fee schedule amount as calculated in paragraph (a) of this section.

[62 FR 59101, Oct. 31, 1997]

§ 414.21 Medicare payment basis.

Medicare payment is based on the lesser of the actual charge or the applicable fee schedule amount.

[62 FR 59101, Oct. 31, 1997]

§ 414.22 Relative value units (RVUs).

CMS establishes RVUs for physicians' work, practice expense, and malpractice insurance.

(a) *Physician work RVUs*—(1) *General rule*. Physician work RVUs are established using a relative value scale in which the value of physician work for a particular service is rated relative to the value of work for other physician services.

(2) *Special RVUs for anesthesia and radiology services)*—(i) *Anesthesia services*. The rules for determining RVUs for anesthesia services are set forth in § 414.46.

(ii) *Radiology services*. CMS bases the RVUs for all radiology services on the relative value scale developed under section 1834(b)(1)(A) of the Act, with appropriate modifications to ensure that the RVUs established for radiology services that are similar or related to other physician services are consistent with the RVUs established for those similar or related services.

(b) *Practice expense RVUs*. (1) Practice expense RVUs are computed for each

service or class of service by applying average historical practice cost percentages to the estimated average allowed charge during the 1991 base period.

(2) The average practice expense percentage for a service or class of services is computed as follows:

(i) Multiply the average practice expense percentage for each specialty by the proportion of a particular service or class of service performed by that specialty.

(ii) Add the products for all specialties.

(3) For services furnished beginning calendar year (CY) 1994, for which 1994 practice expense RVUs exceed 1994 work RVUs and that are performed in office settings less than 75 percent of the time, the 1994, 1995, and 1996 practice expense RVUs are reduced by 25 percent of the amount by which they exceed the number of 1994 work RVUs. Practice expense RVUs are not reduced to less than 128 percent of 1994 work RVUs.

(4) For services furnished beginning January 1, 1998, practice expense RVUs for certain services are reduced to 110 percent of the work RVUs for those services. The following two categories of services are excluded from this limitation:

(i) The service is provided more than 75 percent of the time in an office setting; or

(ii) The service is one described in section 1848(c)(2)(G)(v) of the Act, codified at 42 U.S.C. 1395w–4(c)(2)(G). Section 1848(c)(2)(G)(v) of the Act refers to the 1998 proposed resource-based practice expense RVUs (as specified in the June 18, 1997 physician fee schedule proposed rule (62 FR 33158)) for the specific site, either in-office or out-of-office, increased from its 1997 practice expense RVUs.)

(5) For services furnished beginning January 1, 1999, the practice expense RVUs are based on 75 percent of the practice expense RVUs applicable to services furnished in 1998 and 25 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2000, the practice expense RVUs are based on 50 percent of the practice expense RVUs applicable to services furnished in 1998 and 50 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2001, the practice expense RVUs are based on 25 percent of the practice expense RVUs applicable to services furnished in 1998 and 75 percent of the relative practice expense resources involved in furnishing the service. For services furnished in 2002 and subsequent years, the practice expense RVUs are based entirely on relative practice expense resources.

(i) Usually there are two levels of practice expense RVUs that correspond to each code.

(A) *Facility practice expense RVUs*. The lower facility practice expense RVUs apply to services furnished to patients in the hospital, skilled nursing facility, community mental health center, or in an ambulatory surgical center when the physician performs procedures on the ASC approved procedures list. (The facility practice expense RVUs for a particular code may not be greater than the non-facility RVUs for the code.)

(B) *Non-facility practice expense RVUs*. The higher non-facility practice expense RVUs apply to services performed in a physician's office, a patient's home, an ASC if the physician is performing a procedure not on the ASC approved procedures list, a nursing facility, or a facility or institution other than a hospital or skilled nursing facility, community mental health center, or ASC performing an ASC approved procedure.

(C) *Outpatient therapy services*. Outpatient therapy services billed under the physician fee schedule are paid using the non-facility practice expense RVU component.

(ii) Only one practice expense RVU per code can be applied for each of the following services: services that have only technical component practice expense RVUs or only professional component practice expense RVUs; evaluation and management services, such as hospital or nursing facility visits, that are furnished exclusively in one setting; and major surgical services.

(6)(i) CMS establishes criteria for supplemental surveys regarding specialty practice expenses submitted to

CMS that may be used in determining practice expense RVUs.

(ii) Any CMS-designated specialty group may submit a supplemental survey.

(iii) CMS will consider for use in determining practice expense RVUs for the physician fee schedule survey data and related materials submitted to CMS by March 1, 2004 to determine CY 2005 practice expense RVUs and by March 1, 2005 to determine CY 2006 practice expense RVUs.

(c) *Malpractice insurance RVUs.* (1) Malpractice insurance RVUs are computed for each service or class of services by applying average malpractice insurance historical practice cost percentages to the estimated average allowed charge during the 1991 base period.

(2) The average historical malpractice insurance percentage for a service or class of services is computed as follows:

(i) Multiply the average malpractice insurance percentage for each specialty by the proportion of a particular service or class of services performed by that specialty.

(ii) Add all the products for all the specialties.

(3) For services furnished in the year 2000 and subsequent years, the malpractice RVUs are based on the relative malpractice insurance resources.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42493, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993; 62 FR 59102, Oct. 31, 1997; 63 FR 58910, Nov. 2, 1998; 64 FR 59441, Nov. 2, 1999; 65 FR 25668, May 3, 2000; 65 FR 65440, Nov. 1, 2000; 67 43558, June 28, 2002; 68 FR 63261, Nov. 7, 2003]

§ 414.24 Review, revision, and addition of RVUs for physician services.

(a) *Interim values for new and revised HCPCS level 1 and level 2 codes.* (1) CMS establishes interim RVUs for new services and for codes for which definitions have changed.

(2) CMS publishes a notice in the FEDERAL REGISTER to announce interim RVUs and seek public comment on them. The RVUs are effective prospectively for services furnished beginning on the effective date specified in the notice.

(3) After considering public comments, CMS revises, if necessary, the interim RVUs and announces those revisions in a final notice published in the FEDERAL REGISTER. Any revisions in the RVUs are effective prospectively for services furnished beginning on the effective date specified in the final notice.

(b) *Revision of RVUs for established HCPCS level 1 and level 2 codes.* (1) CMS publishes a proposed notice in the FEDERAL REGISTER to announce changes in RVUs for established codes and provides an opportunity for public comment no less often than every 5 years.

(2) After considering public comments, CMS publishes a final notice in the FEDERAL REGISTER to announce revisions to RVUs.

(3) The RVU revisions are effective prospectively for services furnished beginning on the effective date specified in the final notice.

(c) *Values for local codes (HCPCS Level 3).* (1) Carriers establish relative values for local codes for services not included in HCPCS levels 1 or 2.

(2) Carriers must obtain prior approval from CMS to establish local codes for services that meet the definition of ''physician services'' in § 414.2.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992]

§ 414.26 Determining the GAF.

CMS establishes a GAF for each service in each fee schedule area.

(a) *Geographic indices.* CMS uses the following indices to establish the GAF:

(1) An index that reflects one-fourth of the difference between the relative value of physicians' work effort in each of the different fee schedule areas as determined under § 414.22(a) and the national average of that work effort.

(2) An index that reflects the relative costs of the mix of goods and services comprising practice expenses (other than malpractice expenses) in each of the different fee schedule areas as determined under § 414.22(b) compared to the national average of those costs.

(3) An index that reflects the relative costs of malpractice expenses in each of the different fee schedule areas as determined under § 414.22(c) compared to the national average of those costs.

(b) *Class-specific practice cost indices.* If the application of a single index to different classes of services would be

substantially inequitable because of differences in the mix of goods and services comprising practice expenses for the different classes of services, more than one index may be established under paragraph (a)(2) of this section.

(c) *Computation of GAF.* The GAF for each fee schedule area is the sum of the physicians' work adjustment factor, the practice expense adjustment factor, and the malpractice cost adjustment factor, as defined in this section:

(1) The geographic physicians' work adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the work component and the geographic physicians' work index value established under paragraph (a)(1) of this section.

(2) The geographic practice expense adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the practice expense component, multiplied by the geographic practice cost index (GPCI) value established under paragraph (a)(2) of this section.

(3) The geographic malpractice adjustment factor for a service is the product of the proportion of the total relative value for the service that reflects the RVUs for the malpractice component, multiplied by the GPCI value established under paragraph (a)(3) of this section.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992]

§ 414.28 Conversion factors.

CMS establishes CFs in accordance with section 1848(d) of the Act.

(a) *Base-year CFs.* CMS established the CF for 1992 so that had section 1848 of the Act applied during 1991, it would have resulted in the same aggregate amount of payments for physician services as the estimated aggregate amount of these payments in 1991, adjusted by the update for 1992 computed as specified in § 414.30.

(b) *Subsequent CFs.* For calendar years 1993 through 1995, the CF for each year is equal to the CF for the previous year, adjusted in accordance with § 414.30. Beginning January 1, 1996, the CF for each calendar year may be further adjusted so that adjustments to the fee schedule in accordance with section 1848(c)(2)(B)(ii) of the Act do not cause total expenditures under the fee schedule to differ by more than $20 million from the amount that would have been spent if these adjustments had not been made.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 60 FR 53877, Oct. 18, 1995; 60 FR 63177, Dec. 8, 1995]

§ 414.30 Conversion factor update.

Unless Congress acts in accordance with section 1848(d)(3) of the Act—

(a) *General rule.* The CF update for a CY equals the Medicare Economic Index increased or decreased by the number of percentage points by which the percentage increase in expenditures for physician services (or for a particular category of physician services, such as surgical services) in the second preceding FY over the third preceding FY exceeds the performance standard rate of increase established for the second preceding FY.

(b) *Downward adjustment.* The downward adjustment may not exceed the following:

(1) For CYs 1992 and 1993, 2 percentage points.

(2) For CY 1994, 2.5 percentage points.

(3) For CYs 1995 and thereafter, 5 percentage points.

[55 FR 23441, June 8, 1990, as amended at 60 FR 63177, Dec. 8, 1995; 61 FR 42385, Aug. 15, 1996]

§ 414.32 Determining payments for certain physicians' services furnished in facility settings.

(a) *Definition.* As used in this section, *facility settings* include the following facilities:

(1) Hospital outpatient departments, including clinics and emergency rooms.

(2) Hospital inpatient departments.

(3) Comprehensive outpatient rehabilitation facilities.

(4) Comprehensive inpatient rehabilitation facilities.

(5) Inpatient psychiatric facilities.

(6) Skilled nursing facilities.

(b) *General rule.* If physicians' services of the type routinely furnished in physicians' offices are furnished in facility settings before January 1, 1999, the physician fee schedule amount for

those services is determined by reducing the practice expense RVUs for the services by 50 percent. For services furnished on or after January 1, 1999, the practice expense RVUs are determined in accordance with § 414.22(b)(5).

(c) *Services covered by the reduction.* CMS establishes a list of services routinely furnished in physicians' offices nationally. Services furnished at least 50 percent of the time in physicians' offices are subject to this reduction.

(d) *Services excluded from the reduction.* The reduction established under this section does not apply to the following:

(1) Rural health clinic services.

(2) Surgical services not on the ambulatory surgical center covered list of procedures published under § 416.65(c) of this chapter when furnished in an ambulatory surgical center.

(3) Anesthesiology services and diagnostic and therapeutic radiology services.

[58 FR 63687, Dec. 2, 1993, as amended at 60 FR 63177, Dec. 8, 1995; 62 FR 59102, Oct. 31, 1997; 63 FR 58911, Nov. 2, 1998; 64 FR 25457, May 12, 1999]

§ 414.34 Payment for services and supplies incident to a physician's service.

(a) *Medical supplies.* (1) Except as otherwise specified in this paragraph, office medical supplies are considered to be part of a physician's practice expense, and payment for them is included in the practice expense portion of the payment to the physician for the medical or surgical service to which they are incidental.

(2) If physician services of the type routinely furnished in provider settings are furnished in a physician's office, separate payment may be made for certain supplies furnished incident to that physician service if the following requirements are met:

(i) It is a procedure that can safely be furnished in the office setting in appropriate circumstances.

(ii) It requires specialized supplies that are not routinely available in physicians' offices and that are generally disposable.

(iii) It is furnished before January 1, 1999.

(3) For the purpose of paragraph (a)(2) of this section, provider settings include only the following settings:

(i) Hospital inpatient and outpatient departments.

(ii) Ambulatory surgical centers.

(4) For the purpose of paragraph (a)(2) of this section, ''routinely furnished in provider settings'' means furnished in inpatient or outpatient hospital settings or ambulatory surgical centers more than 50 percent of the time.

(5) CMS establishes a list of services for which a separate supply payment may be made under this section.

(6) The fee schedule amount for supplies billed separately is not subject to a GPCI adjustment.

(b) *Services of nonphysicians that are incident to a physician's service.* Services of nonphysicians that are covered as incident to a physician's service are paid as if the physician had personally furnished the service.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 58911, Nov. 2, 1998]

§ 414.36 Payment for drugs incident to a physician's service.

Payment for drugs incident to a physician's service is made in accordance with § 405.517 of this chapter.

§ 414.39 Special rules for payment of care plan oversight.

(a) *General.* Except as specified in paragraphs (b) and (c) of this section, payment for care plan oversight is included in the payment for visits and other services under the physician fee schedule. For purposes of this section a nonphysician practitioner (NPP) is a nurse practitioner, clinical nurse specialist or physician assistant.

(b) *Exception.* Separate payment is made under the following conditions for physician care plan oversight services furnished to beneficiaries who receive HHA and hospice services that are covered by Medicare:

(1) The care plan oversight services require recurrent physician supervision of therapy involving 30 or more minutes of the physician's time per month.

(2) Payment is made to only one physician per patient for services furnished during a calendar month period. The

physician must have furnished a service requiring a face-to-face encounter with the patient at least once during the 6-month period before the month for which care plan oversight payment is first billed. The physician may not have a significant ownership interest in, or financial or contractual relationship with, the HHA in accordance with § 424.22(d) of this chapter. The physician may not be the medical director or employee of the hospice and may not furnish services under an arrangement with the hospice.

(3) If a physician furnishes care plan oversight services during a post-operative period, payment for care plan oversight services is made if the services are documented in the patient's medical record as unrelated to the surgery.

(c) *Special rules for payment of care plan oversight provided by nonphysician practitioners for beneficiaries who receive HHA services covered by Medicare.*

(1) An NPP can furnish physician care plan oversight (but may not certify a patient as needing home health services) only if the physician who signs the plan of care provides regular ongoing care under the same plan of care as does the NPP billing for care plan oversight and either—

(i) The physician and NPP are part of the same group practice; or

(ii) If the NPP is a nurse practitioner or clinical nurse specialist, the physician signing the plan of care also has a collaborative agreement with the NPP; or

(iii) If the NPP is a physician assistant, the physician signing the plan of care is also the physician who provides general supervision of physician assistant services for the practice.

(2) Payment may be made for care plan oversight services furnished by an NPP when:

(i) The NPP providing the care plan oversight has seen and examined the patient;

(ii) The NPP providing care plan oversight is not functioning as a consultant whose participation is limited to a single medical condition rather than multi-disciplinary coordination of care; and

(iii) The NPP providing care plan oversight integrates his or her care with that of the physician who signed the plan of care.

[59 FR 63463, Dec. 8, 1994; 60 FR 49, Jan. 3, 1995; 60 FR 36733, July 18, 1995 as amended at 69 FR 66423, Nov. 15, 2004; 70 FR 16722, Apr. 1, 2005]

§ 414.40 Coding and ancillary policies.

(a) *General rule.* CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes.

(b) *Specific types of policies.* CMS establishes uniform national ancillary policies necessary to implement the fee schedule for physician services. These include, but are not limited to, the following policies:

(1) Global surgery policy (for example, post- and pre-operative periods and services, and intra-operative services).

(2) Professional and technical components (for example, payment for services, such as an EEG, which typically comprise a technical component (the taking of the test) and a professional component (the interpretation)).

(3) Payment modifiers (for example, assistant-at-surgery, multiple surgery, bilateral surgery, split surgical global services, team surgery, and unusual services).

§ 414.42 Adjustment for first 4 years of practice.

(a) *General rule.* For services furnished during CYs 1992 and 1993, except as specified in paragraph (b) of this section, the fee schedule payment amount or prevailing charge must be phased in as specified in paragraph (d) of this section for physicians, physical therapists (PTs), occupational therapists (OTs), and all other health care practitioners who are in their first through fourth years of practice.

(b) *Exception.* The reduction required in paragraph (d) of this section does not apply to primary care services or to services furnished in a rural area as defined in section 1886(d)(2)(D) of the Act that is designated under section 332(a)(1)(A) of the Public Health Service Act as a Health Professional Shortage Area.

(c) *Definition of years of practice.* (1) The ''first year of practice'' is the first full CY during the first 6 months of which the physician, PT, OT, or other

health care practitioner furnishes professional services for which payment may be made under Medicare Part B, plus any portion of the prior CY if that prior year does not meet the first 6 months test.

(2) The ''second, third, and fourth years of practice'' are the first, second, and third CYs following the first year of practice, respectively.

(d) *Amounts of adjustment*. The fee schedule payment for the service of a new physician, PT, OT, or other health care practitioner is limited to the following percentages for each of the indicated years:

(1) First year—80 percent
(2) Second year—85 percent
(3) Third year—90 percent
(4) Fourth year—95 percent

[57 FR 42493, Sept. 15, 1992, as amended at 58 FR 63687, Dec. 2, 1993]

§ 414.44 Transition rules.

(a) *Adjusted historical payment basis*—(1) *All services other than radiology and nuclear medicine services*. For all physician services other than radiology services, furnished in a fee schedule area, the adjusted historical payment basis (AHPB) is the estimated weighted average prevailing charge applied in the fee schedule area for the service in CY 1991, as determined by CMS without regard to physician specialty and as adjusted to reflect payments for services below the prevailing charge, adjusted by the update established for CY 1992.

(2) *Radiology services*. For radiology services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 1834(b), adjusted by the update established for CY 1992.

(3) *Nuclear medicine services*. For nuclear medicine services, the AHPB is the amount paid for the service in the fee schedule area in CY 1991 under the fee schedule established under section 6105(b) of Public Law 101–239 and section 4102(g) of Public Law 101–508, adjusted by the update established for CY 1992.

(4) *Transition adjustment*. CMS adjusts the AHPB for all services by 5.5 percent to produce budget-neutral payments for 1992.

(b) *Adjustment of 1992 payments for physician services other than radiology services*. For physician services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 115 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 115 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(c) *Adjustment of 1992 payments for radiology services*. For radiology services furnished during CY 1992 the following rules apply:

(1) If the AHPB determined under paragraph (a) of this section is from 85 percent to 109 percent of the fee schedule amount for the area for services furnished in 1992, payment is at the fee schedule amount.

(2) If the AHPB determined under paragraph (a) of this section is less than 85 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB plus 15 percent of the fee schedule amount is substituted for the fee schedule amount.

(3) If the AHPB determined under paragraph (a) of this section is greater than 109 percent of the fee schedule amount for the area for services furnished in 1992, an amount equal to the AHPB minus 9 percent of the fee schedule amount is substituted for the fee schedule amount.

(d) *Computation of payments for CY 1993*. For physician services subject to the transition rules in CY 1992 and furnished during CY 1993, the fee schedule is equal to 75 percent of the amount that would have been paid in the fee schedule area under the 1992 transition rules, adjusted by the amount of the

1993 update, plus 25 percent of the 1993 fee schedule amount.

(e) *Computation of payments for CY 1994.* For physician services subject to the transition rules in CY 1993, and furnished during CY 1994, the fee schedule is equal to 67 percent of the amount that would have been paid in the fee schedule area under the 1993 transition rules, adjusted by the amount of the 1994 update, plus 33 percent of the 1994 fee schedule amount.

(f) *Computation of payments for CY 1995.* For physician services subject to the transition rules in CY 1994 and furnished during CY 1995, the fee schedule is equal to 50 percent of the amount that would have been paid in the fee schedule area under the 1994 transition rules, adjusted by the amount of the 1995 update, plus 50 percent of the 1995 fee schedule amount.

§ 414.46 Additional rules for payment of anesthesia services.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Base unit* means the value for each anesthesia code that reflects all activities other than anesthesia time. These activities include usual preoperative and postoperative visits, the administration of fluids and blood incident to anesthesia care, and monitoring services.

(2) *Anesthesia practitioner*, for the purpose of anesthesia time, means a physician who performs the anesthesia service alone, a CRNA who is not medically directed who performs the anesthesia service alone, or a medically directed CRNA.

(3) *Anesthesia time* means the time during which an anesthesia practitioner is present with the patient. It starts when the anesthesia practitioner begins to prepare the patient for anesthesia services and ends when the anesthesia practitioner is no longer furnishing anesthesia services to the beneficiary, that is, when the beneficiary may be placed safely under postoperative care. Anesthesia time is a continuous time period from the start of anesthesia to the end of an anesthesia service. In counting anesthesia time, the anesthesia practitioner can add blocks of anesthesia time around an interruption in anesthesia time as long as the anesthesia practitioner is furnishing continuous anesthesia care within the time periods around the interruption.

(b) *Determinations of payment amount—Basic rule.* For anesthesia services performed, medically directed, or medically supervised by a physician, CMS pays the lesser of the actual charge or the anesthesia fee schedule amount.

(1) The carrier bases the fee schedule amount for an anesthesia service on the product of the sum of allowable base and time units and an anesthesia-specific CF. The carrier calculates the time units from the anesthesia time reported by the anesthesia practitioner for the anesthesia procedure. The physician who fulfills the conditions for medical direction in § 415.110 (Conditions for payment: Anesthesiology services) reports the same anesthesia time as the medically-directed CRNA.

(2) CMS furnishes the carrier with the base units for each anesthesia procedure code. The base units are derived from the 1988 American Society of Anesthesiologists' Relative Value Guide except that the number of base units recognized for anesthesia services furnished during cataract or iridectomy surgery is four units.

(3) Modifier units are not allowed. Modifier units include additional units charged by a physician or a CRNA for patient health status, risk, age, or unusual circumstances.

(c) *Physician personally performs the anesthesia procedure.*

(1) CMS considers an anesthesia service to be personally performed under any of the following circumstances:

(i) The physician performs the entire anesthesia service alone.

(ii) The physician establishes an attending physician relationship in one or two concurrent cases involving an intern or resident and the service was furnished before January 1, 1994.

(iii) The physician establishes an attending physician relationship in one case involving an intern or resident and the service was furnished on or after January 1, 1994 but prior to January 1, 1996. For services on or after January 1, 1996, the physician must be the teaching physician as defined in

§§ 415.170 through 415.184 of this chapter.

(iv) The physician and the CRNA or AA are involved in a single case and the services of each are found to be medically necessary.

(v) The physician is continuously involved in a single case involving a student nurse anesthetist.

(vi) The physician is continuously involved in a single case involving a CRNA or AA and the service was furnished prior to January 1, 1998.

(2) CMS determines the fee schedule amount for an anesthesia service personally performed by a physician on the basis of an anesthesia-specific fee schedule CF and unreduced base units and anesthesia time units. One anesthesia time unit is equivalent to 15 minutes of anesthesia time, and fractions of a 15-minute period are recognized as fractions of an anesthesia time unit.

(d) *Anesthesia services medically directed by a physician.* (1) CMS considers an anesthesia service to be medically directed by a physician if:

(i) The physician performs the activities described in § 415.110 of this chapter.

(ii) The physician directs qualified individuals involved in two, three, or four concurrent cases.

(iii) Medical direction can occur for a single case furnished on or after January 1, 1998 if the physician performs the activities described in § 415.110 of this chapter and medically directs a single CRNA or AA.

(2) The rules for medical direction differ for certain time periods depending on the nature of the qualified individual who is directed by the physician. If more than two procedures are directed on or after January 1, 1994, the qualified individuals could be AAs, CRNAs, interns, or residents. The medical direction rules apply to student nurse anesthetists only if the physician directs two concurrent cases, each of which involves a student nurse anesthetist or the physician directs one case involving a student nurse anesthetist and the other involving a CRNA, AA, intern, or resident.

(3) Payment for medical direction is based on a specific percentage of the payment allowance recognized for the anesthesia service personally performed by a physician alone. The following percentages apply for the years specified:

(i) CY 1994—60 percent of the payment allowance for personally performed procedures.

(ii) CY 1995—57.5 percent of the payment allowance for personally performed services.

(iii) CY 1996—55 percent of the payment allowance for personally performed services.

(iv) CY 1997—52.5 percent of the payment allowance for personally performed services.

(v) CY 1998 and thereafter—50 percent of the payment allowance for personally performed services.

(e) *Physicians involved with two concurrent cases with residents.* The physician can bill base units and time units based on the amount of time the physician is actually present with the resident during each of two concurrent cases furnished on or after January 1, 2004.

(1) To bill the base units, the physician must be present with the resident during the pre- and post-anesthesia care included in the base units.

(2) If the physician is not present with the resident during pre- and post-anesthesia care, then the physician may bill the case as a medically directed case in accordance with paragraph (d) of this section.

(f) *Physician medically supervises anesthesia services.* If the physician medically supervises more than four concurrent anesthesia services, CMS bases the fee schedule amount on an anesthesia-specific CF and three base units. This represents payment for the physician's involvement in the pre-surgical anesthesia services.

(g) *Payment for medical or surgical services furnished by a physician while furnishing anesthesia services.* (1) CMS allows separate payment under the fee schedule for certain reasonable and medically necessary medical or surgical services furnished by a physician while furnishing anesthesia services to the patient. CMS makes payment for these services in accordance with the general physician fee schedule rules in § 414.20. These services are described in program operating instructions.

(2) CMS makes no separate payment for other medical or surgical services, such as the pre-anesthetic examination of the patient, pre- or post-operative visits, or usual monitoring functions, that are ordinarily included in the anesthesia service.

(h) *Physician involved in multiple anesthesia services.* If the physician is involved in multiple anesthesia services for the same patient during the same operative session, the carrier makes payment according to the base unit associated with the anesthesia service having the highest base unit value and anesthesia time that encompasses the multiple services. The carrier makes payment for add-on anesthesia codes according to program operating instructions.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993; 60 FR 63177, Dec. 8, 1995; 64 FR 59441, Nov. 2, 1999; 67 FR 80041, Dec. 31, 2002; 68 FR 63261, Nov. 7, 2003]

§ 414.48 Limits on actual charges of nonparticipating suppliers.

(a) *General rule.* A supplier, as defined in § 400.202 of this chapter, who is nonparticipating and does not accept assignment may charge a beneficiary an amount up to the limiting charge described in paragraph (b) of this section.

(b) *Specific limits.* For items or services paid under the physician fee schedule, the limiting charge is 115 percent of the fee schedule amount for nonparticipating suppliers. For items or services CMS excludes from payment under the physician fee schedule (in accordance with section 1848 (j)(3) of the Act), the limiting charge is 115 percent of 95 percent of the payment basis applicable to participating suppliers as calculated in § 414.20(b).

[58 FR 63687, Dec. 2, 1993, as amended at 62 FR 59102, Oct. 31, 1997]

§ 414.50 Physician billing for purchased diagnostic tests.

(a) *General rule.* For services covered under section 1861(s)(3) of the Act and paid for under this part 414 subpart A, if a physician bills for a diagnostic test performed by an outside supplier, the payment to the physician less the applicable deductibles and coinsurance may not exceed the lowest of the following amounts:

(1) The supplier's net charge to the physician.

(2) The physician's actual charge.

(3) The fee schedule amount for the test that would be allowed if the supplier billed directly.

(b) *Restriction on payment.* The physician must identify the supplier and indicate the supplier's net charge for the test. If the physician fails to provide this information, CMS makes no payment to the physician and the physician may not bill the beneficiary.

(1) Physicians who accept Medicare assignment may bill beneficiaries for only the applicable deductibles and coinsurance.

(2) Physicians who do not accept Medicare assignment may not bill the beneficiary more than the payment amount described in paragraph (a) of this section.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 34328, June 24, 1998]

§ 414.52 Payment for physician assistants' services.

Allowed amounts for the services of a physician assistant furnished beginning January 1, 1992 and ending December 31, 1997, may not exceed the limits specified in paragraphs (a) through (c) of this section. Allowed amounts for the services of a physician assistant furnished beginning January 1, 1998, may not exceed the limits specified in paragraph (d) of this section.

(a) For assistant-at-surgery services, 65 percent of the amount that would be allowed under the physician fee schedule if the assistant-at-surgery service was furnished by a physician.

(b) For services (other than assistant-at-surgery services) furnished in a hospital, 75 percent of the physician fee schedule amount for the service.

(c) For all other services, 85 percent of the physician fee schedule amount for the service.

(d) For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, 85 percent of the physician fee schedule amount that would be allowed

under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

[56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, as amended at 63 FR 58911, Nov. 2, 1998]

§ 414.54 Payment for certified nurse-midwives' services.

For services furnished after December 31, 1991, allowed amounts under the fee schedule established under section 1833(a)(1)(K) of the Act for the payment of certified nurse-midwife services may not exceed 65 percent of the physician fee schedule amount for the service.

§ 414.56 Payment for nurse practitioners' and clinical nurse specialists' services.

(a) *Rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a rural area (as described in section 1861(s)(2)(K)(iii) of the Act) may not exceed the following limits:

(1) For services furnished in a hospital (including assistant-at-surgery services), 75 percent of the physician fee schedule amount for the service.

(2) For all other services, 85 percent of the physician fee schedule amount for the service.

(b) *Non-rural areas.* For services furnished beginning January 1, 1992 and ending December 31, 1997, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in a nursing facility may not exceed 85 percent of the physician fee schedule amount for the service.

(c) *Beginning January 1, 1998.* For services (other than assistant-at-surgery services) furnished beginning January 1, 1998, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount for the service. For assistant-at-surgery services, allowed amounts for the services of a nurse practitioner or clinical nurse specialist may not exceed 85 percent of the physician fee schedule amount that would be allowed under the physician fee schedule if the assistant-at-surgery service were furnished by a physician.

[63 FR 58911, Nov. 2, 1998]

§ 414.58 Payment of charges for physician services to patients in providers.

(a) *Payment under the physician fee schedule.* In addition to the special conditions for payment in §§ 415.100 through 415.130, and § 415.190 of this chapter, CMS establishes payment for physician services to patients in providers under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) *Teaching hospitals.* Services furnished by physicians in teaching hospitals may be made on a reasonable cost basis set forth in § 415.162 of this chapter if the hospital exercises the election described in § 415.160 of this chapter.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, Sept. 15, 1992; 60 FR 63189, Dec. 8, 1995]

§ 414.60 Payment for the services of CRNAs.

(a) *Basis for payment.* The allowance for the anesthesia service furnished by a CRNA, medically directed or not medically directed, is based on allowable base and time units as defined in § 414.46(a). Beginning with CY 1994—

(1) The allowance for an anesthesia service furnished by a medically directed CRNA is based on a fixed percentage of the allowance recognized for the anesthesia service personally performed by the physician alone, as specified in § 414.46(d)(3); and

(2) The CF for an anesthesia service furnished by a CRNA not directed by a physician may not exceed the CF for a service personally performed by a physician.

(b) *To whom payment may be made.* Payment for an anesthesia service furnished by a CRNA may be made to the CRNA or to any individual or entity (such as a hospital, critical access hospital, physician, group practice, or ambulatory surgical center) with which the CRNA has an employment or contract relationship that provides for payment to be made to the individual or entity.

(c) *Condition for payment.* Payment for the services of a CRNA may be made only on an assignment related basis, and any assignment accepted by a CRNA is binding on any other person presenting a claim or request for payment for the service.

[60 FR 63178, Dec. 8, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 59441, Nov. 2, 1999]

§ 414.62 Fee schedule for clinical psychologist services.

The fee schedule for clinical psychologist services is set at 100 percent of the amount determined for corresponding services under the physician fee schedule.

[62 FR 59102, Oct. 31, 1997]

§ 414.63 Payment for outpatient diabetes self-management training.

(a) Payment under the physician fee schedule. Except as provided in paragraph (d) of this section, payment for outpatient diabetes self-management training is made under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) To whom payment may be made. Payment may be made to an entity approved by CMS to furnish outpatient diabetes self-management training in accordance with part 410, subpart H of this chapter.

(c) Limitation on payment. Payment may be made for training sessions actually attended by the beneficiary and documented on attendance sheets.

(d) Payments made to those not paid under the physician fee schedule. Payments may be made to other entities not routinely paid under the physician fee schedule, such as hospital outpatient departments, ESRD facilities, and DME suppliers. The payment equals the amounts paid under the physician fee schedule.

(e) Other conditions for fee-for-service payment. The beneficiary must meet the following conditions:

(1) Has not previously received initial training for which Medicare payment was made under this benefit.

(2) Is not receiving services as an inpatient in a hospital, SNF, hospice, or nursing home.

(3) Is not receiving services as an outpatient in an RHC or FQHC.

[65 FR 83153, Dec. 29, 2000]

§ 414.64 Payment for medical nutrition therapy.

(a) *Payment under the physician fee schedule.* Medicare payment for medical nutrition therapy is made under the physician fee schedule in accordance with subpart B of this part. Payment to non-physician professionals, as specified in paragraph (b) of this section, is the lesser of the actual charges or 80 percent of 85 percent of the physician fee schedule amount.

(b) *To whom payment may be made.* Payment may be made to a registered dietician or nutrition professional qualified to furnish medical nutrition therapy in accordance with part 410, subpart G of this chapter.

(c) *Effective date of payment.* Medicare pays suppliers of medical nutrition therapy on or after the effective date of enrollment of the supplier at the carrier.

(d) *Limitation on payment.* Payment is made only for documented nutritional therapy sessions actually attended by the beneficiary.

(e) *Other conditions for fee-for-service payment.* Payment is made only if the beneficiary:

(1) Is not an inpatient of a hospital, SNF, nursing home, or hospice.

(2) Is not receiving services in an RHC, FQHC or ESRD dialysis facility.

[66 FR 55332, Nov. 1, 2001]

§ 414.65 Payment for telehealth services.

(a) *Professional service.* Medicare payment for the professional service via an interactive telecommunications system is made according to the following limitations:

(1) The Medicare payment amount for office or other outpatient visits, consultation, individual psychotherapy, psychiatric diagnostic interview examination, pharmacologic management and end stage renal disease related services included in the monthly capitation payment (except for one visit per month to examine the access site) furnished via an interactive telecommunications system is equal to the

current fee schedule amount applicable for the service of the physician or practitioner.

(2) Only the physician or practitioner at the distant site may bill and receive payment for the professional service via an interactive telecommunications system.

(3) Payments made to the physician or practitioner at the distant site, including deductible and coinsurance, for the professional service may not be shared with the referring practitioner or telepresenter.

(b) *Originating site facility fee.* For telehealth services furnished on or after October 1, 2001:

(1) For services furnished on or after October 1, 2001 through December 31, 2002, the payment amount to the originating site is the lesser of the actual charge or the originating site facility fee of $20. For services furnished on or after January 1 of each subsequent year, the facility fee for the originating site will be updated by the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act.

(2) Only the originating site may bill for the originating site facility fee and only on an assignment-related basis. The distant site physician or practitioner may not bill for or receive payment for facility fees associated with the professional service furnished via an interactive telecommunications system.

(c) *Deductible and coinsurance apply.* The payment for the professional service and originating site facility fee is subject to the coinsurance and deductible requirements of sections 1833(a)(1) and (b) of the Act.

(d) *Assignment required for physicians, practitioners, and originating sites.* Payment to physicians, practitioners, and originating sites is made only on an assignment-related basis.

(e) *Sanctions.* A distant site practitioner or originating site facility may be subject to the applicable sanctions provided for in chapter IV, part 402 and chapter V, parts 1001, 1002, and 1003 of this title if he or she does any of the following:

(1) Knowingly and willfully bills or collects for services in violation of the limitation of this section.

(2) Fails to timely correct excess charges by reducing the actual charge billed for the service in an amount that does not exceed the limiting charge for the service or fails to timely refund excess collections.

(3) Fails to submit a claim on a standard form for services provided for which payment is made on a fee schedule basis.

(4) Imposes a charge for completing and submitting the standard claims form.

[66 FR 55332, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2003; 69 FR 66424, Nov. 15, 2004]

§ 414.66 Incentive payments for physician scarcity areas.

(a) *Definition.* As used in this section, the following definitions apply.

Physician scarcity area is defined as an area with a shortage of primary care physicians or specialty physicians to the Medicare population in that area.

Primary care physician is defined as a general practitioner, family practice practitioner, general internist, obstetrician or gynecologist.

(b) Physicians' services furnished to a beneficiary in a Physician Scarcity Area (PSA) for primary or specialist care are eligible for a 5 percent incentive payment.

(c) Primary care physicians furnishing services in primary care PSAs are entitled to an additional 5 percent incentive payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

(d) Physicians, as defined in section 1861(r)(1) of the Act, furnishing services in specialist care PSAs are entitled to an additional 5 percent payment above the amount paid under the physician fee schedule for their professional services furnished on or after January 1, 2005 and before January 1, 2008.

[69 FR 66424, Nov. 15, 2004]

§ 414.67 Incentive payments for Health Professional Shortage Areas.

(a) Physicians' services furnished to a beneficiary in a geographic-based Health Professional Shortage Area

(HPSA) are eligible for a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule.

(b) Physicians furnishing services in a geographic-based primary medical care HPSA are entitled to a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule.

(c) Psychiatrists furnishing services in a mental health HPSA are entitled to a 10 percent incentive payment above the amount paid for their professional services under the physician fee schedule. (The only physicians eligible to receive the 10 percent incentive payment in mental health HPSAs that do not overlap with primary care HPSAs are psychiatrists.)

[69 FR 66424, Nov. 15, 2004]

Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies

SOURCE: 66 FR 45176, Aug. 28, 2001, unless otherwise noted.

§ 414.100 Purpose.

This subpart implements fee schedules for PEN items and services as authorized by section 1842(s) of the Act.

§ 414.102 General payment rules.

(a) General rule. For items and services furnished on or after January 1, 2002, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of—

(1) The actual charge for the item or service; or

(2) The fee schedule amount for the item or service, as determined in accordance with §§ 414.104.

(b) Payment classification. (1) CMS or the carrier determines fee schedules for Parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, as specified in § 414.104.

(2) CMS designates the specific items and services in each category through program instructions.

(c) Updating the fee schedule amounts. For each year subsequent to 2002, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding year.

§ 414.104 PEN Items and Services.

(a) Payment Rules. Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

(b) Fee schedule amount. The fee schedule amount for payment for an item or service furnished in 2002 is the lesser of—

(i) The reasonable charge from 1995; or

(ii) The reasonable charge that would have been used in determining payment for 2002.

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

§ 414.200 Purpose.

This subpart implements sections 1834 (a) and (h) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment and prosthetic and orthotic devices for Medicare beneficiaries.

[57 FR 57689, Dec. 7, 1992]

§ 414.202 Definitions.

For purposes of this subpart, the following definitions apply:

Covered item update means the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U) for the 12-month period ending with June of the previous year.

Durable medical equipment means equipment, furnished by a supplier or a home health agency that—

(1) Can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose;

(3) Generally is not useful to an individual in the absence of an illness or injury; and

(4) Is appropriate for use in the home. (See § 410.38 of this chapter for a description of when an institution qualifies as a home.)

Prosthetic and orthotic devices means—

(1) Devices that replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, and replacement of such devices and supplies;

(2) One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; and

(3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition.

The following are neither prosthetic nor orthotic devices—

(1) Parenteral and enteral nutrients, supplies, and equipment;

(2) Intraocular lenses;

(3) Medical supplies such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care that are furnished by an HHA as part of home health services under § 409.40(e) of this chapter;

(4) Dental prostheses.

Region means those carrier service areas administered by CMS regional offices.

[57 FR 57689, Dec. 7, 1992]

§ 414.210 General payment rules.

(a) *General rule*. For items furnished on or after January 1, 1989, except as provided in paragraphs (c) and (d) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§ 414.220 through 414.232.

(b) *Payment classification*. (1) The carrier determines fee schedules for the following classes of equipment and devices:

(i) Inexpensive or routinely purchased items, as specified in § 414.220.

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222.

(iii) Certain customized items, as specified in § 414.224.

(iv) Oxygen and oxygen equipment, as specified in § 414.226.

(v) Prosthetic and orthotic devices, as specified in § 414.228.

(vi) Other durable medical equipment (capped rental items), as specified in § 414.229.

(vii) Transcutaneous electrical nerve stimulators (TENS), as specified in § 414.232.

(2) CMS designates the items in each class of equipment or device through its program instructions.

(c) *Exception for certain HHAs*. Public HHAs and HHAs that furnish services or items free-of-charge or at nominal prices to a significant number of low-income patients, as defined in § 413.13(a) of this chapter, are paid on the basis of 80 percent of the fee schedule amount determined in accordance with the provision of §§ 414.220 through 414.230.

(d) *Prohibition on special limits*. For items furnished on or after January 1, 1989 and before January 1, 1991, neither CMS nor a carrier may establish a special reasonable charge for items covered under this subpart on the basis of inherent reasonableness as described in § 405.502(g) of this chapter.

(e) *Maintenance and servicing*. (1) *General rule*. Except as provided in paragraph (e)(2) of this section, the carrier pays the reasonable and necessary charges for maintenance and servicing of purchased equipment. Reasonable and necessary charges are those made for parts and labor not otherwise covered under a manufacturer's or supplier's warranty. Payment is made, as needed, in a lump sum based on the carrier's consideration of the item. Payment is not made for maintenance and servicing of a rented item other than the maintenance and servicing fee for other durable medical equipment, as described in § 414.229(e).

(2) *Exception*. For items purchased on or after June 1, 1989, no payment is made under the provisions of paragraph (e)(1) of this section for the maintenance and servicing of:

(i) Items requiring frequent and substantial servicing, as defined in § 414.222(a);

(ii) Capped rental items, as defined in § 414.229(a), that are not purchased in accordance with § 414.229(d); and

(iii) Oxygen equipment, as defined in §414.226.

(f) *Replacement of equipment.* Except as provided in §414.229(g), if a purchased item of DME or a prosthetic or orthotic device paid for under this subpart has been in continuous use by the patient for the equipment's reasonable useful lifetime or if the carrier determines that the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement equipment, payment is made on a purchase basis.

[57 FR 57689, Dec. 7, 1992]

§414.220 Inexpensive or routinely purchased items.

(a) *Definitions.* (1) *Inexpensive equipment* means equipment the average purchase price of which did not exceed $150 during the period July 1986 through June 1987.

(2) *Routinely purchased equipment* means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

(3) *Accessories.* Effective January 1, 1994, accessories used in conjunction with a nebulizer, aspirator, or ventilator excluded from §414.222 meet the definitions of ''inexpensive equipment'' and ''routinely purchased equipment'' in paragraphs (a)(1) and (a)(2) of this section, respectively.

(b) *Payment rules.* (1) Subject to the limitation in paragraph (b)(3) of this section, payment for inexpensive and routinely purchased items is made on a rental basis or in a lump sum amount for purchase of the item based on the applicable fee schedule amount.

(2) Effective January 1, 1994, payment for ostomy supplies, tracheostomy supplies, urologicals, and surgical dressings not furnished as incident to a physician's professional service or furnished by an HHA is made using the methodology for the inexpensive and routinely purchased class.

(3) The total amount of payments made for an item may not exceed the fee schedule amount recognized for the purchase of that item.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for payment of purchase or rental of inexpensive or routinely purchased items furnished in 1989 and 1990 is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for inexpensive or routinely purchased items that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item. A separate determination of an average reasonable charge is made for rental equipment, new purchased equipment, and used purchased equipment.

(2) The carrier adjusts the amount determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the local payment amounts for years after 1990.* For each year subsequent to 1990, the local payment amounts of the preceding year are increased or decreased by the covered item update. For 1991 and 1992, the covered item update is reduced by 1 percentage point.

(e) *Calculating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedule amounts are equal to the national limited payment amount.

(f) *Calculating the national limited payment amount.* The national limited payment amount is computed as follows:

(1) The 1991 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 67 percent of the local payment amount plus 33 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts; or

(iii) The sum of 67 percent of the local payment amount plus 33 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(2) The 1992 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 33 percent of the local payment amount plus 67 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

(iii) The sum of 33 percent of the local payment amount plus 67 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

(3) For 1993, the national limited payment amount is equal to one of the following:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts.

(ii) 100 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts.

(iii) 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(4) For 1994 and subsequent years, the national limited payment amount is equal to one of the following:

(i) If the local payment amount is not in excess of the median, nor less than 85 percent of the median, of all local payment amounts—100 percent of the local payment amount.

(ii) If the local payment amount exceeds the median—100 percent of the median of all local payment amounts.

(iii) If the local payment amount is less than 85 percent of the median—85 percent of the median of all local payment amounts.

(g) *Payment for surgical dressings.* For surgical dressings furnished after December 31, 1993, the national limited payment amount is computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates for 1993 and 1994.

[57 FR 57689, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995]

§ 414.222 Items requiring frequent and substantial servicing.

(a) *Definition.* Items requiring frequent and substantial servicing in order to avoid risk to the beneficiary's health are the following:

(1) Ventilators (except those that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices).

(2) Continuous and intermittent positive pressure breathing machines.

(3) Continuous passive motion machines.

(4) Other items specified in CMS program instructions.

(5) Other items identified by the carrier.

(b) *Payment rule.* Rental payments for items requiring frequent and substantial servicing are made on a monthly basis, and continue until medical necessity ends.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for items requiring frequent and substantial servicing is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for rental of items requiring frequent and substantial servicing that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier adjusts the amounts determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) *Updating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedules are determined using

the methodology contained in paragraphs (d), (e), and (f) of §414.220.

(e) *Transition to other payment classes.* For purposes of calculating the 15-month rental period, beginning January 1, 1994, if an item has been paid for under the frequent and substantial servicing class and is subsequently paid for under another payment class, the rental period begins with the first month of continuous rental, even if that period began before January 1, 1994. For example, if the rental period began on July 1, 1993, the carrier must use this date as beginning the first month of rental. Likewise, for purposes of calculating the 10-month purchase option, the rental period begins with the first month of continuous rental without regard to when that period started. For example, if the rental period began in August 1993, the 10-month purchase option must be offered to the beneficiary in May 1994, the tenth month of continuous rental.

[57 FR 57690, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995]

§414.224 Customized items.

(a) *Criteria for a customized item.* To be considered a customized item for payment purposes under paragraph (b) of this section, a covered item (including a wheelchair) must be uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of a physician and be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

(b) *Payment rule.* Payment is made on a lump sum basis for the purchase of a customized item based on the carrier's individual consideration and judgment of a reasonable payment amount for each customized item. The carrier's individual consideration takes into account written documentation on the costs of the item including at least the cost of labor and materials used in customizing an item.

[56 FR 65998, Dec. 20, 1991, as amended at 58 FR 34919, June 30, 1993]

§414.226 Oxygen and oxygen equipment.

(a) *Payment rules.* (1) Payment for rental of oxygen equipment and purchase of oxygen contents is made based on a monthly fee schedule amount.

(2) Monthly fee schedule payments continue until medical necessity ends.

(b) *Monthly fee schedule amount.* (1) Monthly fee schedule amounts are separately calculated for the following items:

(i) Stationary oxygen equipment and oxygen contents (stationary and portable oxygen contents).

(ii) Portable oxygen equipment only.

(iii) Stationary and portable oxygen contents only.

(iv) Portable oxygen contents only.

(2) For 1989 and 1990, the monthly fee schedule amounts are the local payment amounts determined as follows:

(i) The carrier determines the base local average monthly payment rate equal to the total reasonable charges for the item for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving the item for the same period. In determining the local average monthly payment rate, the following limitations apply:

(A) Purchase charges for oxygen systems are not included as items classified under paragraph (b)(1)(i) of this section.

(B) Purchase charges for portable equipment are not included as items classified under paragraph (b)(1)(ii) of this section.

(ii) The carrier determines the local monthly payment amount equal to 0.95 times the base local average monthly payment amount adjusted by the change in the CPI-U for the six-month period ending December 1987.

(3) For years after 1990, the fee schedule amounts are determined using the methodology contained in §414.220 (d), (e), and (f).

(c) *Application of monthly fee schedule amounts.* (1) The fee schedule amount for items described in paragraph (b)(1)(i) of this section is paid when the beneficiary rents a stationary oxygen system.

(2) Subject to the limitation set forth in paragraph (d)(2) of this section, the

fee schedule amount for items described in paragraph (b)(1)(ii) of this section is paid when the beneficiary rents a portable oxygen system.

(3) The fee schedule amount for items described in paragraph (b)(1)(iii) of this section is paid when the beneficiary owns a stationary gaseous or liquid oxygen system.

(4) The fee schedule amount for items described in paragraph (b)(1)(iv) of this section is paid when the beneficiary owns or rents a portable gaseous or portable liquid oxygen system and uses either a stationary oxygen concentrator or no stationary oxygen system.

(d) *Volume adjustments:* (1) The fee schedule amount for an item described in paragraph (b)(1)(i) of this section is adjusted as follows:

(i) If the attending physician prescribes an oxygen flow rate exceeding four liters per minute, the fee schedule amount is increased by 50 percent, subject to the limit in paragraph (d)(2) of this section.

(ii) If the attending physician prescribes an oxygen flow rate of less than one liter per minute, the fee schedule amount is decreased by 50 percent.

(2) If portable oxygen equipment is used and the prescribed oxygen flow rate exceeds four liters per minute, the total fee schedule amount recognized for payment is limited to the higher of—

(i) The sum of the monthly fee schedule amount for the items described in paragraphs (b)(1)(i) and (ii) of this section; or

(ii) The adjusted fee schedule amount described in paragraph (d)(1)(i) of this section.

(3) In establishing the volume adjustment for those beneficiaries whose physicians prescribe varying flow rates, the following rules apply:

(i) If the prescribed flow rate is different for stationary oxygen equipment than for portable oxygen equipment, the flow rate for the stationary equipment is used.

(ii) If the prescribed flow rate is different for the patient at rest than for the patient at exercise, the flow rate for the patient at rest is used.

(iii) If the prescribed flow rate is different for nighttime use and daytime use, the average of the two flow rates is used.

[57 FR 57690, Dec. 7, 1992]

§ 414.228 Prosthetic and orthotic devices.

(a) *Payment rule.* Payment is made on a lump-sum basis for prosthetic and orthotic devices subject to this subpart.

(b) *Fee schedule amounts.* The fee schedule amount for prosthetic and orthotic devices is determined as follows:

(1) The carrier determines a base local purchase price equal to the average reasonable charge for items purchased during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier determines a local purchase price equal to the following:

(i) For 1989 and 1990, the base local purchase price is adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(ii) For 1991 through 1993, the local purchase price for the preceding year is adjusted by the applicable percentage increase for the year. The applicable percentage increase is equal to 0 percent for 1991. For 1992 and 1993, the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(iii) For 1994 and 1995, the applicable percentage increase is 0 percent.

(iv) For all subsequent years the applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(3) CMS determines the regional purchase price equal to the following:

(i) For 1992, the average (weighted by the relative volume of all claims among carriers) of the local purchase prices for the carriers in the region.

(ii) For 1993 and subsequent years, the regional purchase price for the preceding year adjusted by the applicable percentage increase for the year.

(4) CMS determines a purchase price equal to the following:

(i) For 1989, 1990 and 1991, 100 percent of the local purchase price.

(ii) For 1992, 75 percent of the local purchase price plus 25 percent of the regional purchase price.

(iii) For 1993, 50 percent of the local purchase price plus 50 percent of the regional purchase price.

(iv) For 1994 and subsequent years, 100 percent of the regional purchase price.

(5) For 1992 and subsequent years, CMS determines a national average purchase price equal to the unweighted average of the purchase prices determined under paragraph (b)(4) of this section for all carriers.

(6) CMS determines the fee schedule amount equal to 100 percent of the purchase price determined under paragraph (b)(4) of this section, subject to the following limitations:

(i) For 1992, the amount cannot be greater than 125 percent nor less than 85 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(ii) For 1993 and subsequent years, the amount cannot be greater than 120 percent of the national average nor less than 90 percent of the national average purchase price determined under paragraph (b)(5) of this section.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

§ 414.229 Other durable medical equipment—capped rental items.

(a) *General payment rule.* Subject to the limitation set forth in paragraph (b) of this section, payment is made on a rental or purchase option basis for other durable medical equipment that is not subject to the payment provisions set forth in §§ 414.220 through 414.228.

(b) *Fee schedule amounts for rental.* (1) For 1989 and 1990, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section subject to the following limitation: For 1989 and 1990, the fee schedule amount cannot be greater than 115 percent nor less than 85 percent of the prevailing charge, as determined under § 405.504 of this chapter, established for rental of the item in January 1987, as adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991 and subsequent years, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 7.5 percent of the purchase price for each of the remaining months.

(c) *Determination of purchase price.* The purchase price of other covered durable medical equipment is determined as follows:

(1) For *1989 and 1990.* (i) The carrier determines a base local purchase price amount equal to the average of the purchase prices submitted on an assignment-related basis of new items supplied during the 6-month period ending December 1986.

(ii) The purchase price is equal to the base local purchase price adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For *1991.* (i) The local payment amount is the purchase price for the preceding year adjusted by the covered item update for 1991 and decreased by the percentage by which the average of the reasonable charges for claims paid for all other items described in § 414.229, is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988.

(ii) The purchase price for 1991 is the national limited payment amount as determined using the methodology contained in § 414.220(f).

(3) *For years after 1991.* The purchase price is determined using the methodology contained in paragraphs (d) through (f) of § 414.220.

(d) *Purchase option.* Suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month and, for power-driven wheelchairs, the purchase option must also be made available at the time the equipment is initially furnished.

(1) Suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the supplier first furnishes the item. Payment must be on a lump-sum fee schedule purchase basis if the beneficiary chooses

the purchase option. The purchase fee is the amount established in § 414.229(c).

(2) Suppliers must offer beneficiaries the option of converting capped rental items (including power-driven wheelchairs not purchased when initially furnished) to purchased equipment during their 10th continuous rental month. Beneficiaries have one month from the date the supplier makes the offer to accept the purchase option.

(i) If the beneficiary does not accept the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months. After 15 months of rental payments have been paid, the supplier must continue to provide the item without charge, other than a charge for maintenance and servicing fees, until medical necessity ends or Medicare coverage ceases. A period of continuous use is determined under the provisions in § 414.230.

(ii) If the beneficiary accepts the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 13 months. On the first day after 13 continuous rental months during which payment is made, the supplier must transfer title to the equipment to the beneficiary.

(e) *Payment for maintenance and servicing.* (1) The carrier establishes a reasonable fee for maintenance and servicing for each rented item of other durable medical equipment. The fee may not exceed 10 percent of the purchase price recognized as determined under paragraph (c) of this section.

(2) Payment of the fee for maintenance and servicing of other durable medical equipment that is rented is made only for equipment that continues to be used after 15 months of rental payments have been made and is limited to the following:

(i) For the first 6-month period, no payments are to be made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period.

(3) Payment for maintenance and servicing DME purchased in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, is made on the basis of reasonable and necessary charges.

(f) *Transition to the fee schedules.* For purposes of computing the 10-month or 15-month period of continuous use for other durable medical equipment, as described in § 414.230, the carrier counts the first month that the beneficiary continuously rented the equipment without regard to whether that month occurred before January 1, 1989 or after. If a beneficiary's 15-month rental period ends prior to January 1, 1989, no further purchase or rental payments are to be made except for maintenance and servicing of equipment as described in paragraph (e) of this section.

(g) *Replacement of equipment.* If the item of equipment has been in continuous use by the patient on either a rental or purchase basis for the equipment's useful lifetime, or if the carrier determines that the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement equipment, payment is made on a rental or purchase basis in accordance with paragraph (a) of this section or on a lump-sum purchase basis if a purchase agreement had been entered into in accordance with paragraph (d) of this section.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

§ 414.230 Determining a period of continuous use.

(a) *Scope.* This section sets forth the rules that apply in determining a period of continuous use for rental of durable medical equipment.

(b) *Continuous use.* A period of continuous use begins with the first month of medical need and lasts until a beneficiary's medical need for a particular item of durable medical equipment ends.

(c) *Temporary interruption.* (1) A period of continuous use allows for temporary interruptions in the use of equipment.

(2) An interruption of not longer than 60 consecutive days plus the days remaining in the rental month in which use ceases is temporary, regardless of the reason for the interruption.

(3) Unless there is a break in medical necessity that lasts lnnger than 60 consecutive days plus the days remaining in the rental month in which use ceases, medical necessity is presumed to continue.

(d) *Criteria for a new rental period.* If an interruption in the use of equipment continues for more than 60 consecutive days plus the days remaining in the rental month in which use ceases, a new rental period begins if the supplier submits all of the following information—

(1) A new prescription.

(2) New medical necessity documentation.

(3) A statement describing the reason for the interruption and demonstrating that medical necessity in the prior episode ended.

(e) *Beneficiary moves.* A permanent or temporary move made by a beneficiary does not constitute an interruption in the period of continuous use.

(f) *New equipment.* If a beneficiary changes equipment or requires additional equipment based on a physician's prescription, and the new or additional equipment is found to be necessary, a new period of continuous use begins for the new or additional equipment. A new period of continuous use does not begin for base equipment that is modified by an addition.

(g) *New supplier.* If a beneficiary changes suppliers, a new period of continuous use does not begin.

[56 FR 50823, Oct. 9, 1991, as amended at 57 FR 57111, Dec. 3, 1992]

§414.232 Special payment rules for transcutaneous electrical nerve stimulators (TENS).

(a) *General payment rule.* Except as provided in paragraph (b) of this section, payment for TENS is made on a purchase basis with the purchase price determined using the methodology for purchase of inexpensive or routinely purchased items as described in §414.220. The payment amount for TENS computed under §414.220(c)(2) is reduced according to the following formula:

(1) Effective April 1, 1990—the original payment amount is reduced by 15 percent.

(2) Effective January 1, 1991—the reduced payment amount in paragraph (a)(1) is reduced by 15 percent.

(3) Effective January 1, 1994—the reduced payment amount in paragraph (a)(1) is reduced by 45 percent.

(b) *Exception.* In order to permit an attending physician time to determine whether the purchase of the TENS is medically appropriate for a particular patient, two months of rental payments may be made in addition to the purchase price. The rental payments are equal to 10 percent of the purchase price.

[57 FR 57692, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995]

Subpart E—Determination of Reasonable Charges Under the ESRD Program

§414.300 Scope of subpart.

This subpart sets forth criteria and procedures for payment of the following services furnished to ESRD patients:

(a) Physician services related to renal dialysis.

(b) Physician services related to renal transplantation.

(c) Home dialysis equipment, supplies, and support services.

(d) Epoetin (EPO) furnished by a supplier of home dialysis equipment and supplies to a home dialysis patient for use in the home.

[55 FR 23441, June 8, 1990, as amended at 56 FR 43710, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994]

§414.310 Determination of reasonable charges for physician services furnished to renal dialysis patients.

(a) *Principle.* Physician services furnished to renal dialysis patients are subject to payment if the services are

otherwise covered by the Medicare program and if they are considered reasonable and medically necessary in accordance with section 1862(a)(1)(A) of the Act.

(b) *Scope and applicability*—(1) *Scope.* This section pertains to physician services furnished to the following patients:

(i) Outpatient maintenance dialysis patients who dialyze—

(A) In an independent or hospital-based ESRD facility, or

(B) At home.

(ii) Hospital inpatients for which the physician elects to continue payment under the monthly capitation payment (MCP) method described in § 414.314.

(2) *Applicability.* These provisions apply to routine professional services of physicians. They do not apply to administrative services performed by physicians, which are paid for as part of a prospective payment for dialysis services made to the facility under § 413.170 of this chapter.

(c) *Definitions.* For purposes of this section, the following definitions apply:

Administrative services are physician services that are differentiated from routine professional services and other physician services because they are supervision, as described in the definition of ''supervision of staff'' of this section, or are not related directly to the care of an individual patient, but are supportive of the facility as a whole and of benefit to patients in general. Examples of administrative services include supervision of staff, staff training, participation in staff conferences and in the management of the facility, and advising staff on the procurement of supplies.

Dialysis session is the period of time that begins when the patient arrives at the facility and ends when the patient departs from the facility. In the case of home dialysis, the period begins when the patient prepares for dialysis and generally ends when the patient is disconnected from the machine. In this context, a dialysis facility includes only those parts of the building used as a facility. It does not include any areas used as a physician's office.

Medical direction, in contrast to supervision of staff, is a routine professional service that entails substantial direct involvement and the physical presence of the physician in the delivery of services directly to the patient.

Routine professional services include all physicians' services furnished during a dialysis session and all services listed in paragraph (d) of this section that meet the following requirements:

(1) They are personally furnished by a physician to an individual patient.

(2) They contribute directly to the diagnosis or treatment of an individual patient.

(3) They ordinarily must be performed by a physician.

Supervision of staff, in contrast to medical direction, is an administrative service that does not necessarily require the physician to be present at the dialysis session. It is a general activity primarily concerned with monitoring performance of and giving guidance to other health care personnel (such as nurses and dialysis technicians) who deliver services to patients.

(d) *Types of routine professional services.* Routine professional services include at least all of the following services when medically appropriate:

(1) Visits to the patient during dialysis, and review of laboratory test results, nurses' notes and any other medical documentation, as a basis for—

(i) Adjustment of the patient's medication or diet, or the dialysis procedure;

(ii) Prescription of medical supplies; and

(iii) Evaluation of the patient's psychosocial status and the appropriateness of the treatment modality.

(2) Medical direction of staff in delivering services to a patient during a dialysis session.

(3) Pre-dialysis and post-dialysis examinations, or examinations that could have been furnished on a pre-dialysis or post-dialysis basis.

(4) Insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(e) *Payment for routine professional services.* Beginning August 7, 1990, routine professional services furnished by physicians may be paid under either the ''initial method'' of payment described in § 414.313, (if all of the physicians at the facility elect the initial

method) or under the ''physician MCP method'' described in §414.314. Physician services furnished after July 31, 1983 and before August 6, 1990, are payable only under the MCP method described in §414.314.

§414.313 Initial method of payment.

(a) *Basic rule.* Under this method, the intermediary pays the facility for routine professional services furnished by physicians. Payment is in the form of an add-on to the facility's composite rate payment, which is described in part 413, subpart H of this subchapter.

(b) *Services for which payment is not included in the add-on payment.* (1) Physician administrative services are considered to be facility services and are paid for as part of the facility's composite rate.

(2) The carrier pays the physician or the beneficiary (as appropriate) under the reasonable charge criteria set forth in subpart E of part 405 of this chapter for the following services:

(i) Physician services that must be furnished at a time other than during the dialysis session (excluding pre-dialysis and post-dialysis examinations and examinations that could have been furnished on a pre-dialysis or post-dialysis basis), such as monthly and semi-annual examinations to review health status and treatment.

(ii) Physician surgical services other than insertion of catheters for patients who are on peritoneal dialysis and do not have indwelling catheters.

(iii) Physician services furnished to hospital inpatients who were not admitted solely to receive maintenance dialysis.

(iv) Administration of hepatitis B vaccine.

(c) *Physician election of the initial method.* (1) Each physician in a facility must submit to the appropriate carrier and intermediary that serve the facility a statement of election of the initial method of payment for all the ESRD facility patients that he or she attends.

(2) The initial method of payment applies to dialysis services furnished beginning with the second calendar month after the month in which all physicians in the facility elect the initial method and continues until the effective date of a termination of the election described in paragraph (d) of this section.

(d) *Termination of the initial method.* (1) Physicians may terminate the initial method of payment by written notice to the carrier(s) that serves each physician and to the intermediary that serves the facility.

(2) If the notice terminating the initial method is received by the carrier(s) and intermediary—

(i) On or before November 1, the effective date of the termination is January 1 of the year following the calendar year in which the termination notice is received by the carrier(s) and intermediary; or

(ii) After November 1, the effective date of the termination is January 1 of the second year after the calendar year in which the notice is received by the carrier(s) and intermediary.

(e) *Determination of payment amount.* The factors used in determining the add-on amount are related to program experience. They are re-evaluated periodically and may be adjusted, as determined necessary by CMS, to maintain the payment at a level commensurate with the prevailing charges of other physicians for comparable services.

(f) *Publication of payment amount.* Revisions to the add-on amounts are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[55 FR 23441, June 8, 1990, as amended at 62 FR 43674, Aug. 15, 1997]

§414.314 Monthly capitation payment method.

(a) *Basic rules.* (1) Under the monthly capitation payment (MCP) method, the carrier pays an MCP amount for each patient, to cover all professional services furnished by the physician, except those listed in paragraph (b) of this section.

(2) The carrier pays the MCP amount, subject to the deductible and coinsurance provisions, either to the physician if the physician accepts assignment or to the beneficiary if the physician does not accept assignment.

(3) The MCP method recognizes the need of maintenance dialysis patients for physician services furnished periodically over relatively long periods of

time, and the capitation amounts are consistent with physicians' charging patterns in their localities.

(4) Payment of the capitation amount for any particular month is contingent upon the physician furnishing to the patient all physician services required by the patient during the month, except those listed in paragraph (b) of this section.

(5) Payment for physician administrative services (§ 414.310) is made to the dialysis facility as part of the facility's composite rate (part 413, subpart H of this subchapter) and not to the physician under the MCP.

(b) *Services not included in the MCP.* (1) Services that are not included in the MCP and which may be paid in accordance with the reasonable charge rules set forth in subpart E of part 405 of this chapter are limited to the following:

(i) Administration of hepatitis B vaccine.

(ii) Covered physician services furnished by another physician when the patient is not available to receive, or the attending physician is not available to furnish, the outpatient services as usual (see paragraph (b)(3) of this section).

(iii) Covered physician services furnished to hospital inpatients, including services related to inpatient dialysis, by a physician who elects not to continue to receive the MCP during the period of inpatient stay.

(iv) Surgical services, including declotting of shunts, other than the insertion of catheters for patients on maintenance peritoneal dialysis who do not have indwelling catheters.

(v) Needed physician services that are—

(A) Furnished by the physician furnishing renal care or by another physician;

(B) Not related to the treatment of the patient's renal condition; and

(C) Not furnished during a dialysis session or an office visit required because of the patient's renal condition.

(2) For the services described in paragraph (b)(1)(v) of this section, the following rules apply:

(i) The physician must provide documentation to show that the services are not related to the treatment of the patient's renal condition and that additional visits are required.

(ii) The carrier's medical staff, acting on the basis of the documentation and appropriate medical consultation obtained by the carrier, determines whether additional payment for the additional services is warranted.

(3) The MCP is reduced in proportion to the number of days the patient is—

(i) Hospitalized and the physician elects to bill separately for services furnished during hospitalization; or

(ii) Not attended by the physician or his or her substitute for any reason, including when the physician is not available to furnish patient care or when the patient is not available to receive care.

(c) *Determination of payment amount.* The amount of payment for the MCP is determined under the Medicare physician fee schedule described in this part 414.

[55 FR 23441, June 8, 1990, as amended at 59 FR 63463, Dec. 8, 1994; 62 FR 43674, Aug. 15, 1997]

§ 414.316 Payment for physician services to patients in training for self-dialysis and home dialysis.

(a) For each patient, the carrier pays a flat amount that covers all physician services required to create the capacity for self-dialysis and home dialysis.

(b) CMS determines the amount on the basis of program experience and reviews it periodically.

(c) The payment is made at the end of the training course, is subject to the deductible and coinsurance provisions, and is in addition to any amounts payable under the initial or MCP methods set forth in §§ 414.313 and 414.314, respectively.

(d) If the training is not completed, the payment amount is proportionate to the time spent in training.

§ 414.320 Determination of reasonable charges for physician renal transplantation services.

(a) *Comprehensive payment for services furnished during a 60-day period.* (1) The comprehensive payment is subject to the deductible and coinsurance provisions and is for all surgeon services furnished during a period of 60 days in

connection with a renal transplantation, including the usual preoperative and postoperative care, and for immunosuppressant therapy if supervised by the transplant surgeon.

(2) Additional sums, in amounts established on the basis of program experience, may be included in the comprehensive payment for other surgery performed concurrently with the transplant operation.

(3) The amount of the comprehensive payment may not exceed the lower of the following:

(i) The actual charges made for the services.

(ii) Overall national payment levels established under the ESRD program and adjusted to give effect to variations in physician's charges throughout the nation. (These adjusted amounts are the maximum allowances in a carrier's service area for renal transplantation surgery and related services by surgeons.)

(4) Maximum allowances computed under these instructions are revised at the beginning of each calendar year to the extent permitted by the lesser of the following:

(i) Changes in the economic index as described in §405.504(a)(3)(i) of this chapter.

(ii) Percentage changes in the weighted average of the carrier's prevailing charges (before adjustment by the economic index) for—

(A) A unilateral nephrectomy; or

(B) Another medical or surgical service designated by CMS for this purpose.

(b) *Other payments*. Payments for covered medical services furnished to the transplant recipient by other specialists, as well as for services by the transplant surgeon after the 60-day period covered by the comprehensive payment, are made under the reasonable charge criteria set forth in §405.502 (a) through (d) of this chapter. The payments for physicians' services in connection with renal transplantations are changed on the basis of program experience and the expected advances in the medical art for this operation.

§414.330 Payment for home dialysis equipment, supplies, and support services.

(a) *Equipment and supplies*—(1) *Basic rule*. Except as provided in paragraph (a)(2) of this section, Medicare pays for home dialysis equipment and supplies only under the prospective payment rates established at §413.170.

(2) *Exception*. If the conditions in subparagraphs (a)(2) (i) through (iv) of this section are met, Medicare pays for home analysis equipment and supplies on a reasonable charge basis in accordance with subpart E (Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians) of part 405, but the amount of payment may not exceed the limit for equipment and supplies in paragraph (c)(2) of this section.

(i) The patient elects to obtain home dialysis equipment and supplies from a supplier that is not a Medicare approved dialysis facility.

(ii) The patient certifies to CMS that he or she has only one supplier for all home dialysis equipment and supplies. This certification is made on CMS Form 382 (the ''ESRD Beneficiary Selection'' form).

(iii) In writing, the supplier—

(A) Agrees to receive Medicare payment for home dialysis supplies and equipment only on an assignment-related basis; and

(B) Certifies to CMS that it has a written agreement with one Medicare approved dialysis facility or, if the beneficiary is also entitled to military or veteran's benefits, one military or Veterans Administration hospital, for each patient. (See subpart U of part 405 of this chapter for the requirements for a Medicare approved dialysis facility.) Under the agreement, the facility or military or VA hospital agrees to the following:

(*1*) To furnish all home dialysis support services for each patient in accordance with subpart U (Conditions for Coverage of Suppliers of ESRD Services) of this chapter. (§410.52 sets forth the scope and conditions of Medicare Part B coverage of home dialysis services, supplies, and equipment.)

(*2*) To furnish institutional dialysis services and supplies. (§410.50 sets forth

the scope and conditions for Medicare Part B coverage of institutional dialysis services and supplies.)

(*3*) To furnish dialysis-related emergency services.

(*4*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are covered under the composite rate established at § 413.170 and to arrange for the laboratory to seek payment from the facility. The facility then includes these laboratory services in its claim for payment for home dialysis support services.

(*5*) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are not covered under the composite rate established at § 413.170 and for which the laboratory files a Medicare claim directly.

(*6*) To furnish all other necessary dialysis services and supplies (that is, those which are not home dialysis equipment and supplies).

(*7*) To satisfy all documentation, recordkeeping and reporting requirements in subpart U (Conditions for Coverage of Suppliers of ESRD Services) of this chapter. This includes maintaining a complete medical record of ESRD related items and services furnished by other parties. The facility must report, on the forms required by CMS or the ESRD network, all data for each patient in accordance with subpart U.

(iv) The facility with which the agreement is made must be located within a reasonable distance from the patient's home (that is, located so that the facility can actually furnish the needed services in a practical and timely manner, taking into account variables like the terrain, whether the patient's home is located in an urban or rural area, the availability of transportation, and the usual distances traveled by patients in the area to obtain health care services).

(b) *Support services*—(1) *Basic rule*. Except as provided in paragraph (b)(2) of this section, Medicare pays for support services only under the prospective payment rates established in § 413.170 of this chapter.

(2) *Exceptions*. If the patient elects to obtain home dialysis equipment and supplies from a supplier that is not an approved ESRD facility, Medicare pays for support services, other than support services furnished by military or VA hospitals referred to in paragraph (a)(2)(iii)(B) of this section, under paragraphs (b)(2) (i) and (ii) of this section but in no case may the amount of payment exceed the limit for support services in paragraph (c)(1) of this section:

(i) For support services furnished by a hospital-based ESRD facility, Medicare pays on a reasonable cost basis in accordance with part 413 of this chapter.

(ii) For support services furnished by an independent ESRD facility, Medicare pays on the basis of reasonable charges that are related to costs and allowances that are reasonable when the services are furnished in an effective and economical manner.

(c) *Payment limits*—(1) *Support services*. The amount of payment for home dialysis support services is limited to the national average Medicare-allowed charge per patient per month for home dialysis support services, as determined by CMS, plus the median cost per treatment for all dialysis facilities for laboratory tests included under the composite rate, as determined by CMS, multiplied by the national average number of treatments per month.

(2) *Equipment and supplies*. Payment for home dialysis equipment and supplies is limited to an amount equal to the result obtained by subtracting the support services payment limit in paragraph (c)(1) of this section from the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent) of the national median payment as determined by CMS that would have been made under the prospective payment rates established in § 413.170 of this chapter for hospital-based facilities.

(3) *Notification of changes to the payment limits*. Updated data are incorporated into the payment limits when the prospective payment rates established at § 413.170 of this chapter are updated, and changes are announced by notice in the FEDERAL REGISTER without a public comment period. Revisions of the methodology for determining the limits are published in the FEDERAL

REGISTER in accordance with the Department's established rulemaking procedures.

[57 FR 54187, Nov. 17, 1992]

§414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies.

(b) Payment is made in accordance with the rules set forth in §413.170 of this chapter.

[56 FR 43710, Sept. 4, 1991]

Subparts F–G [Reserved]

Subpart H—Fee Schedule for Ambulance Services

SOURCE: 67 FR 9132, Feb. 27, 2002, unless otherwise noted.

§414.601 Purpose.

This subpart implements section 1834(l) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(l) of the Act requires that, except for services furnished by certain critical access hospitals (see §413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule.

§414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively referred to as ''ground'') ambulance services and to air ambulance services unless otherwise specified:

Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service.

Advanced life support (ALS) intervention means a procedure that is, in accordance with State and local laws, required to be furnished by ALS personnel.

Advanced life support, level 1 (ALS1) means transportation by ground ambulance vehicle, medically necessary supplies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

Advanced life support, level 2 (ALS2) means either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures:

(1) Manual defibrillation/cardioversion.

(2) Endotracheal intubation.

(3) Central venous line.

(4) Cardiac pacing.

(5) Chest decompression.

(6) Surgical airway.

(7) Intraosseous line.

Advanced life support (ALS) personnel means an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. The EMT-Intermediate is defined as an individual who is qualified, in accordance with State and local laws, as an EMT-Basic and who is also qualified in accordance with State and local laws to perform essential advanced techniques and to administer a limited number of medications. The EMT-Paramedic is defined as possessing the qualifications of the EMT-Intermediate and also, in accordance with State and local laws, as having enhanced skills that include being able to administer additional interventions and medications.

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by an individual who is

qualified in accordance with State and local laws as an emergency medical technician-basic (EMT-Basic). These laws may vary from State to State. For example, only in some States is an EMT-Basic permitted to operate limited equipment on board the vehicle, assist more qualified personnel in performing assessments and interventions, and establish a peripheral intravenous (IV) line.

Conversion factor (CF) is the dollar amount established by CMS that is multiplied by relative value units to produce ground ambulance service base rates.

Emergency response means responding immediately at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance entity begins as quickly as possible to take the steps necessary to respond to the call.

Fixed wing air ambulance (FW) means transportation by a fixed wing aircraft that is certified as a fixed wing air ambulance and such services and supplies as may be medically necessary.

Geographic adjustment factor (GAF) means the practice expense (PE) portion of the geographic practice cost index (GPCI) from the physician fee schedule as applied to a percentage of the base rate. For ground ambulance services, the PE portion of the GPCI is applied to 70 percent of the base rate for each level of service. For air ambulance services, the PE portion of the GPCI is applied to 50 percent of the applicable base rate.

Goldsmith modification means the recognition of rural areas within certain Standard Metropolitan Statistical Areas wherein a census tract is deemed to be rural when located within a large metropolitan county of at least 1,225 square miles, but is so isolated from the metropolitan core of that county by distance or physical features as to be more rural than urban in character.

Loaded mileage means the number of miles the Medicare beneficiary is transported in the ambulance vehicle.

Paramedic ALS intercept (PI) means EMT-Paramedic services furnished by an entity that does not furnish the ground ambulance transport, provided the services meet the requirements specified in § 410.40(c) of this chapter.

Point of pick-up means the location of the beneficiary at the time he or she is placed on board the ambulance.

Relative value units (RVUs) means a value assigned to a ground ambulance service.

Rotary wing air ambulance (RW) means transportation by a helicopter that is certified as an ambulance and such services and supplies as may be medically necessary.

Rural adjustment factor (RAF) means an adjustment applied to the base payment rate when the point of pick-up is located in a rural area.

Rural area means an area located outside a Metropolitan Statistical Area (MSA), or, in New England, a New England County Metropolitan Area (NECMA), or an area within an MSA or NECMA that is identified as rural by the Goldsmith modification.

Specialty care transport (SCT) means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

[67 FR 9132, Feb. 27, 2002, as amended at 68 FR 67693, Dec. 5, 2003]

§ 414.610 Basis of payment.

(a) *Method of payment.* Medicare payment for ambulance services is based on the lesser of the actual charge or the applicable fee schedule amount. The fee schedule payment for ambulance services equals a base rate for the level of service plus payment for mileage and applicable adjustment factors. Except for services furnished by certain critical access hospitals or entities owned and operated by them, as described in § 413.70(b) of this chapter, all ambulance services are paid under the fee schedule specified in this subpart (regardless of the vehicle furnishing the service).

(b) *Mandatory assignment.* Effective with implementation of the ambulance fee schedule described in §414.601 (that is, for services furnished on or after April 1, 2002), all payments made for ambulance services are made only on an assignment-related basis. Ambulance suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts. Violations of this requirement may subject the provider or supplier to sanctions, as provided by law (part 402 of this chapter).

(c) *Formula for computation of payment amounts.* The fee schedule payment amount for ambulance services is computed according to the following provisions:

(1) *Ground ambulance service levels.* The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate. For services furnished during the period July 1, 2004 through December 31, 2006, ambulance services originating in urban areas (both base rate and mileage) are paid based on a rate that is one percent higher than otherwise is applicable under this section, and ambulance services originating in rural areas (both base rate and mileage) are paid based on a rate that is two percent higher than otherwise is applicable under this section. The service-level base rate is then adjusted by the GAF. Compare this amount to the actual charge. The lesser of the actual charge or the GAF adjusted base rate amount is added to the lesser of the actual mileage charges or the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is applied to the ground mileage rate to determine the appropriate payment rates. The RVU scale for the ambulance fee schedule is as follows:

Service level	Relative value units (RVUs)
BLS	1.00
BLS-Emergency	1.60
ALS1	1.20
ALS1-Emergency	1.90
ALS2	2.75
SCT	3.25
PI	1.75

(2) *Air ambulance service levels.* The base payment rate for the applicable type of air ambulance service is adjusted by the GAF and, when applicable, by the appropriate RAF to determine the amount of payment. Air ambulance services have no CF or RVUs. This amount is compared to the actual charge. The lesser of the charge or the adjusted GAF rate amount is added to the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is also applied to the air mileage rate.

(3) *Loaded mileage.* Payment is based on loaded miles. Payment for air mileage is based on loaded miles flown as expressed in statute miles. There are three mileage payment rates: a rate for FW services, a rate for RW services, and a rate for all levels of ground transportation.

(4) *Geographic adjustment factor (GAF).* For ground ambulance services, the PE portion of the GPCI from the physician fee schedule is applied to 70 percent of the base rate for ground ambulance services. For air ambulance services, the PE portion of the physician fee schedule GPCI is applied to 50 percent of the base rate for air ambulance services.

(5) *Rural adjustment factor (RAF).* (i) For ground ambulance services where the point of pickup is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles and by 25 percent for miles 18 through 50. The standard mileage rate applies to every mile over 50 miles. For air ambulance services where the point of pickup is in a rural area, the total payment is increased by 50 percent; that is, the rural adjustment factor applies to the sum of the base rate and the mileage rate.

(ii) For services furnished during the period July 1, 2004 through December 31, 2009, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural

population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

(6) *Multiple patients*. The allowable amount per beneficiary for a single ambulance transport when more than one patient is transported simultaneously is based on the total number of patients (both Medicare and non-Medicare) on board. If two patients are transported simultaneously, then the payment allowance for the beneficiary (or for each of them if both patients are beneficiaries) is equal to 75 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus 50 percent of the applicable mileage payment allowance. If three or more patients are transported simultaneously, the payment allowance for the beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus the applicable mileage payment allowance divided by the number of patients on board.

(7) *Payment rate for mileage greater than 50 miles*. For services furnished during the period July 1, 2004 through December 31, 2008, each loaded ambulance mile greater than 50 (that is, miles 51 and greater) for ambulance transports originating in either urban areas or in rural areas are paid based on a rate that is 25 percent higher than otherwise is applicable under this section.

(d) *Payment*. Payment, in accordance with this subpart, represents payment in full (subject to applicable Medicare Part B deductible and coinsurance requirements as described in subpart G of part 409 of this chapter or in subpart I of part 410 of this chapter) for all services, supplies, and other costs for an ambulance service furnished to a Medicare beneficiary. No direct payment will be made under this subpart if billing for the ambulance service is required to be consolidated with billing for another benefit for which payment may be made under this chapter.

(e) *Point of pick-up*. The zip code of the point of pick-up must be reported on each claim for ambulance services so that the correct GAF and RAF may be applied, as appropriate.

(f) *Updates*. The CF, the air ambulance base rates, and the mileage rates are updated annually by an inflation factor established by law. The inflation factor is based on the consumer price index for all urban consumers (CPI-U) (U.S. city average) for the 12-month period ending with June of the previous year.

(g) *Adjustments*. The Secretary will annually review rates and will adjust the CF and air ambulance rates if actual experience under the fee schedule is significantly different from the assumptions used to determine the initial CF and air ambulance rates. The CF and air ambulance rates will not be adjusted solely because of changes in the total number of ambulance transports.

[67 FR 9132, Feb. 27, 2002, as amended at 68 FR 67693, Dec. 5, 2003; 69 FR 40292, July 1, 2004]

§ 414.615 Transition to the ambulance fee schedule.

The fee schedule for ambulance services will be phased in over 5 years beginning April 1, 2002. Subject to the first sentence in § 414.610(a), payment for services furnished during the transition period is made based on a combination of the fee schedule payment for ambulance services and the amount the program would have paid absent the fee schedule for ambulance services, as follows:

(a) *2002 Payment*. For services furnished in 2002, the payment for the service component, the mileage component and, if applicable, the supply component is based on 80 percent of the reasonable charge for independent suppliers or on 80 percent of reasonable cost for providers, plus 20 percent of the ambulance fee schedule amount for the service and mileage components. The reasonable charge or reasonable cost portion of payment in CY 2002 is equal to the supplier's reasonable

charge allowance or provider's reasonable cost allowance for CY 2001, multiplied by the statutory inflation factor for ambulance services.

(b) *2003 Payment*. For services furnished in CY 2003, payment is based on 60 percent of the reasonable charge or reasonable cost, as applicable, plus 40 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2003 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2002, multiplied by the statutory inflation factor for ambulance services.

(c) *2004 Payment*. For services furnished in CY 2004, payment is based on 40 percent of the reasonable charge or reasonable cost, as applicable, plus 60 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2004 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2003, multiplied by the statutory inflation factor for ambulance services.

(d) *2005 Payment*. For services furnished in CY 2005, payment is based on 20 percent of the reasonable charge or reasonable cost, as applicable, plus 80 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2005 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2004, multiplied by the statutory inflation factor for ambulance services.

(e) *2006 and Beyond Payment*. For services furnished in CY 2006 and thereafter, the payment is based solely on the ambulance fee schedule amount.

(f) *Updates*. The portion of the transition payment that is based on the existing payment methodology (that is, the non-fee-schedule portion) is updated annually for inflation by a factor equal to the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending with June of the previous year. The CY 2002 inflation update factor used to update the 2001 payment amounts is applied to the annualized (average) payment amounts for CY 2001. For the period January 1, 2001 through June 30, 2001, the inflation update factor is 2.7 percent. For the period July 1, 2001 through December 31, 2001, the inflation update factor is 4.7 percent. The average for the year is 3.7 percent. Thus, the annualized (average) CY 2001 payment amounts used to derive the CY 2002 payment amounts are equivalent to the CY 2001 payment amounts that would have been determined had the inflation update factor for the entire CY 2001 been 3.7 percent. Both portions of the transition payment (that is, the portion that is based on reasonable charge or reasonable cost and the portion that is based on the ambulance fee schedule) are updated annually for inflation by the inflation factor described in §414.610(f).

(g) *Exception*. There will be no blended payment allowance as described in paragraphs (a), (b), (c), and (d) of this section for ground mileage in those States where the Medicare carrier paid separately for all out-of-county ground ambulance mileage, but did not, before the implementation of the Medicare ambulance fee schedule, make a separate payment for any ground ambulance mileage within the county in which the beneficiary was transported. Payment for ground ambulance mileage in that State will be made based on the full ambulance fee schedule amount for ground mileage. This exception applies only to carrier-processed claims and only in those States in which the carrier paid separately for out-of-county ambulance mileage, but did not make separate payment for any in-county mileage throughout the entire State.

§414.617 Transition from regional to national ambulance fee schedule.

For services furnished during the period July 1, 2004 through December 31, 2009, the amount for the ground ambulance base rate is subject to a floor amount determined by establishing nine fee schedules based on each of the nine census divisions using the same methodology as used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount that is less than or equal to the national ground base rate, then it is not used, and the national FS amount applies. If the regional fee schedule methodology for a given census division results in an amount that is greater than the national ground base rate, then the FS portion of the base rate for that

census division is equal to a blend of the national rate and the regional rate in accordance with the following schedule:

Time period	Regional percent	National percent
7/1/04–12/31/04	80	20
CY 2005	60	40
CY 2006	40	60
CY 2007–CY 2009	20	80
CY 2010 and thereafter	0	100

[69 FR 40292, July 1, 2004]

§ 414.620 Publication of the ambulance fee schedule.

Changes in payment rates resulting from incorporation of the annual inflation factor described in § 414.610(f) will be announced by notice in the FEDERAL REGISTER without opportunity for prior comment. CMS will follow applicable rulemaking procedures in publishing revisions to the fee schedule for ambulance services that result from any factors other than the inflation factor.

§ 414.625 Limitation on review.

There will be no administrative or judicial review under section 1869 of the Act or otherwise of the amounts established under the fee schedule for ambulance services, including the following:

(a) Establishing mechanisms to control increases in expenditures for ambulance services.

(b) Establishing definitions for ambulance services that link payments to the type of services provided.

(c) Considering appropriate regional and operational differences.

(d) Considering adjustments to payment rates to account for inflation and other relevant factors.

(e) Phasing in the application of the payment rates under the fee schedule in an efficient and fair manner.

Subpart I—Payment for Drugs and Biologicals

SOURCE: 69 FR 1116, Jan. 7, 2004, unless otherwise noted.

§ 414.701 Purpose.

This subpart implements section 1842(o) of the Social Security Act by specifying the methodology for determining the payment allowance limit for drugs and biologicals covered under Part B of Title XVIII of the Act (hereafter in this subpart referred to as the ''program'') that are not paid on a cost or prospective payment system basis. Examples of drugs that are subject to the rules contained in this subpart are: drugs furnished incident to a physician's service; durable medical equipment (DME) drugs; separately billable drugs at independent dialysis facilities not under the ESRD composite rate; statutorily covered drugs, for example, influenza, pneumococcal and hepatitis vaccines, antigens, hemophilia blood clotting factor, immunosuppressive drugs and certain oral anti-cancer drugs.

§ 414.704 Definitions.

As used in this subpart, the following definition applies. *Drug* refers to both drugs and biologicals.

§ 414.707 Basis of payment.

(a) *Method of payment.* (1) Payment for a drug in calendar year 2004 is based on the lesser of—

(i) The actual charge on the claim for program benefits; or

(ii) 85 percent of the average wholesale price determined as of April 1, 2003, subject to the exceptions as specified in paragraphs (a)(2) through (a)(8) of this section.

(2) The payment limits for the following drugs are calculated using 95 percent of the average wholesale price:

(i) Blood clotting factors.

(ii) A drug or biological furnished during 2004 that was not available for Medicare payment as of April 1, 2003.

(iii) Pneumococcal and influenza vaccines as well as hepatitis B vaccine that is furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary).

(iv) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(3) The payment limits for infusion drugs furnished through a covered item of durable medical equipment are calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

(4) The payments limits for drugs contained in the following table are calculated based on the percentages of the average wholesale price determined as of April 1, 2003 that are specified in the table.

Drug	Percentage used to calculate 2004 payment limit
EPOETIN ALFA	87
LEUPROLIDE ACETATE	81
GOSERELIN ACETATE	80
RITUXIMAB	81
PACLITAXEL	81
DOCETAXEL	80
CARBOPLATIN	81
IRINOTECAN	80
GEMCITABINE HCL	80
PAMIDRONATE DISODIUM	85
DOLASETRON MESYLATE	80
FILGRASTIM	81
HYLAN G-F 20	82
MYCOPHENOLATE MOFETIL	86
GRANISETRON HCL	80
ONDANSETRON	87
VINORELBINE TARTATE	81
SARGRAMOSTIM	80
TOPOTECAN	84
IPRATROPIUM BROMIDE	80
ALBUTEROL SULFATE	80
IMMUNE GLOBULIN	80
LEUCOVORIN CALCIUM	80
DOXORUBICIN HCL	80
DEXAMETHOSONE SODIUM PHOSPHATE	86
HEPARIN SODIUM LOCK-FLUSH	80
CROMOLYN SODIUM	80
ACETYLCYSTEINE	80

(5) The payment limits for imiglucerase and alglucerase are calculated using 94 percent of the average wholesale price determined as of April 1, 2003.

(6) Exception. The payment limit for a drug otherwise subject to paragraph (a)(1)(ii) or paragraph (a)(4) of this section may be calculated using the percentage of the average wholesale price as the Secretary deems appropriate based on data and information submitted by the drug manufacturer.

(i) The manufacturer must submit data after October 15, 2003 and before January 1, 2004.

(ii) The percentage only applies for drugs furnished on or after April 1, 2004.

(7) In the case of blood and blood products (other than blood clotting factors), the payment limits shall be determined in the same manner as such payment limit was determined on October 1, 2003.

(b) *Mandatory assignment.* Effective with services furnished on or after February 1, 2001, payment for any drug covered under Part B of Medicare may be made on an assignment-related basis only. All billers must accept the program allowed charge as payment in full and may not bill nor collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts, if applicable. Violations of this requirement may subject the supplier to sanctions, as provided by the statute (*See* § 402 of this chapter).

Subpart J—Submission of Manufacturer's Average Sales Price Data

SOURCE: 69 FR 17938, Apr. 6, 2004, unless otherwise noted.

§ 414.800 Purpose.

This subpart implements section 1847A of the Act by specifying the requirements for submission of a manufacturer's average sales price data for certain drugs and biologicals covered under Part B of Title XVIII of the Act that are paid under sections 1842(o)(1)(D), 1847A, and 1881(b)(13)(A)(ii) of the Act.

§ 414.802 Definitions.

As used in this subpart, unless the context indicates otherwise—

Drug means both drugs and biologicals.

Manufacturer means any entity that is engaged in the following (This term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law):

(1) Production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(2) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Unit means the product represented by the 11-digit National Drug code.

§ 414.804 Basis of payment.

(a) *Calculation of manufacturer's average sales price.*

(1) The manufacturer's average sales price for a quarter for a drug or biological represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code (after deducting the types of items and transactions listed in paragraph (a)(2) of this section and excluding sales referenced in paragraph (a)(4) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales referenced in paragraph (a)(4) of this section).

(2) In calculating the manufacturer's average sales price, a manufacturer must deduct the following types of transactions and items:

(i) Volume discounts.

(ii) Prompt pay discounts.

(iii) Cash discounts.

(iv) Free goods that are contingent on any purchase requirement.

(v) Chargebacks and rebates (other than rebates under the Medicaid drug rebate program).

(3) To the extent that data on price concessions, as described in paragraph (a)(2) of this section, are available on a lagged basis, the manufacturer must estimate this amount in accordance with the methodology described in paragraphs (a)(3)(i) through (a)(3)(iv) of this section.

(i) For each such National Drug Code, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period available associated with sales subject to the average sales price reporting requirement divided by the total in dollars for the sales subject to the average sales price reporting requirement for the same 12-month period.

(ii) The manufacturer then multiplies the percentage described in paragraph (a)(3)(i) of this section by the total in dollars for the sales subject to the average sales price reporting requirement for the quarter being submitted. (The manufacturer must carry a sufficient number of decimal places in the calculation of the price concessions percentage in order to round accurately the net total sales amount for the quarter to the nearest whole dollar.) The result of this multiplication is then subtracted from the total in dollars for the sales subject to the average sales price reporting requirement for the quarter being submitted.

(iii) The manufacturer then uses the result of the calculation described in paragraph (a)(3)(ii) of this section as the numerator and the number of units sold in the quarter as the denominator to calculate the manufacturer's average sales price for the National Drug Code in the quarter being submitted.

(iv) *Example.* The total price concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with sales for National Drug Code 12345–6789–01 subject to the ASP reporting requirement equal $200,000. The total in dollars for the sales subject to the average sales price reporting requirement for the same period equals $600,000. The price concessions percentage for this period equals 200,000/600,000 = .33333. The total in dollars for the sales subject to the average sales price reporting requirement for the quarter being reported equals $50,000 for 10,000 units sold. The manufacturer's average sales price calculation for this National Drug Code for this quarter is: $50,000 − (0.33333 × $50,000) = $33,334 (net total sales amount); $33,334/10,000 = $3.33 (average sales price).

(4) In calculating the manufacturer's average sales price, a manufacturer must exclude sales that are exempt from the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the Act.

(5) The manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(6) Each report must be certified by one of the following:

(i) The manufacturer's Chief Executive Officer (CEO).

(ii) The manufacturer's Chief Financial Officer (CFO).

(iii) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

[69 FR 17938, Apr. 6, 2004, as amended at 69 FR 55764, Sept. 16, 2004]

§ 414.806 Penalties associated with the failure to submit timely and accurate ASP data.

Section 1847A(d)(4) specifies the penalties associated with misrepresentations associated with ASP data. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied. Section 1927(b)(3)(C) of the Act, as amended by section 303(i)(4) of the MMA, specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

Subpart K—Payment for Drugs and Biologicals Under Part B

SOURCE: 69 FR 66424, Nov. 15, 2004, unless otherwise noted.

§ 414.900 Basis and scope.

(a) This subpart implements sections 1842(o), 1847A, and 1847B of the Act and outlines two payment methodologies applicable to drugs and biologicals covered under Medicare Part B that are not paid on a cost or prospective payment system basis.

(b) Examples of drugs that are subject to the requirements specified in this subpart are:

(1) Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs.

(2) Separately billable drugs at independent dialysis facilities not under the ESRD composite rate.

(3) Statutorily covered drugs, for example—

(i) Influenza.

(ii) Pneumococcal and Hepatitis B vaccines.

(iii) Antigens.

(iv) Hemophilia blood clotting factor.

(v) Immunosuppressive drugs.

(vi) Certain oral anti-cancer drugs.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005]

§ 414.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Approved CAP vendor means an entity that has been awarded a contract by CMS to participate in the competitive acquisition program under 1847B of the Act.

Bid means an offer to furnish a CAP drug within a category of CAP drugs in a competitive acquisition area for a particular price and time period.

CAP drug means a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

Competitive acquisition area means a geographic area established by the Secretary for purposes of implementing the CAP required by section 1847B of the Act.

Competitive acquisition program (CAP) means a program as defined under section 1847B of the Act.

Designated carrier means an entity assigned by CMS to process and pay claims for drugs and biologicals under the CAP.

Drug means both drugs and biologicals.

Emergency delivery means delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. In each case, this timeframe shall be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid

adversely affecting the product's integrity, safety, or efficacy.

Emergency situation means, for the purposes of the CAP, an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of § 414.906(e) are met.

Local carrier means an entity assigned by CMS to process and pay claims for administration of drugs and biologicals under the CAP.

Manufacturer's average sales price means the price calculated and reported by a manufacturer under part 414, subpart J of this chapter.

Multiple source drug means a drug described by section 1847A(c)(6)(C) of the Act.

Pacific Territories means, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.

Participating CAP physician means a physician electing to participate in the CAP, as described in this subpart. The participating CAP physician must complete and sign the participating CAP physician election agreement. Physicians who do not participate in Medicare but who elect to participate in the CAP must agree to accept assignment for CAP drug administration claims.

Participating CAP physician election agreement means the agreement that the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in this subpart.

Prescription order means a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of this subpart.

Routine delivery means delivery of a drug within 2 business days in appropriate shipping and packaging in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and packaging. In each case, this timeframe will be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Single source drug means a drug described by section 1847A(c)(6)(D) of the Act.

Timely delivery means delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.

Unit is defined as in part 414, subpart J of this chapter.

Wholesale acquisition cost (WAC) means the price described by section 1847A(c)(6)(B) of the Act.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005]

§ 414.904 Average sales price as the basis for payment.

(a) *Method of payment*. Payment for a drug for calendar year 2005 is based on the lesser of—

(1) The actual charge on the claim for program benefits; or

(2) 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

(b) *Multiple source drugs*. (1) *Average sales prices*. The average sales price for all drug products included within the same multiple source drug billing and payment code is the volume-weighted average of the manufacturers' average sales prices for those drug products.

(2) *Calculation of the average sales price*. The average sales price is determined by—

(i) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(ii) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(c) *Single source drugs*. (1) *Average sales price*. The average sales price is the volume-weighted average of the manufacturers' average sales prices for

all National Drug Codes assigned to the drug or biological product.

(2) *Calculation of the average sales price.* The average sales price is determined by computing—

(i) The sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(ii) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(d) *Limitations on the average sales price.* (1) *Wholesale acquisition cost for a single source drug.* The payment limit for a single source drug product is the lesser of 106 percent of the average sales price for the product or 106 percent of the wholesale acquisition cost for the product.

(2) *Payment limit for a drug furnished to an end-stage renal disease patient.* (i) Effective for drugs and biologicals furnished in 2005, the payment for such drugs and biologicals, including erythropoietin, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility and not paid on a cost basis is acquisition cost as determined by the Inspector General report as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 inflated by the percentage increase in the Producer Price Index.

(ii) Except as provided in paragraph (a) of this section, the payment for drugs and biologicals, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility, is based on 106 percent of the average sales price.

(3) *Widely available market price and average manufacturer price.* If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2005, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price.

(e) *Exceptions to the average sales price.* (1) *Vaccines.* The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary), pneumococcal vaccine, and influenza vaccine and are calculated using 95 percent of the average wholesale price.

(2) *Infusion drugs furnished through a covered item of durable medical equipment.* The payment limit for an infusion drug furnished through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003 and is not updated in 2005.

(3) *Blood and blood products.* In the case of blood and blood products (other than blood clotting factors), the payment limits are determined in the same manner as the payment limits were determined on October 1, 2003.

(4) *Payment limit in a case where the average sales price during the first quarter of sales is unavailable.* In the case of a drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price for the drug, the payment limit is based on the wholesale acquisition cost or the applicable Medicare Part B drug payment methodology in effect on November 1, 2003.

(f) Except as otherwise specified (see paragraph (e)(2) of this section) for infusion drugs, the payment limits are updated quarterly.

(g) The payment limit is computed without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(h) The payment amount is subject to applicable deductible and coinsurance.

§414.906 Competitive acquisition program as the basis for payment.

(a) *Program payment.* Beginning in 2006, as an alternative to payment under §414.904, payment for a CAP drug may be made through the CAP if the following occurs:

(1) The CAP drug is supplied under the CAP by an approved CAP vendor as specified in §414.908(b).

(2) The claim for the prescribed drug is submitted by the approved CAP vendor that supplied the drug, and payment is made only to that vendor.

(3) The approved CAP vendor collects applicable deductible and coinsurance with respect to the drug furnished under the CAP only after the drug is administered to the beneficiary.

(4) The approved CAP vendor delivers CAP drugs directly to the participating CAP physician in unopened vials or other original containers as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer and includes language with the shipping material stating that the drug was acquired in a manner consistent with all statutory requirements. If the approved CAP vendor opts to split shipments, the participating CAP physician must be notified in writing which can be included with the initial shipment, and each incremental shipment must arrive at least 2 business days before the anticipated date of administration.

(5) The approved CAP vendor bills Medicare only for the amount of the drug administered to the patient, and the beneficiary's coinsurance will be calculated from the quantity of drug that is administered.

(b) *Exceptions to competitive acquisition.* Specific CAP drugs, including a category of these drugs, may be excluded from the CAP if the application of competitive bidding to these drugs—

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs.

(c) *Computation of payment amount.* (1) Except as specified in paragraph (c)(2) of this section, payment for CAP drugs is based on bids submitted, as a result of the bidding process as described in § 414.910. Based on these bids, a single payment amount for each CAP drug in the competitive acquisition area is determined on the basis of the bids submitted and accepted and updated from the bidding period to the payment year. This single payment amount is then updated on an annual basis based on the approved CAP vendor's reasonable net acquisition costs for that category as determined by CMS based, in part, on information disclosed to CMS and limited by the weighted payment amount established under section 1847A of the Act across all drugs in that category. Adjustment to the payment amounts may be made more often than annually, but no more often than quarterly, in any of the following cases:

(i) Introduction of new drugs.

(ii) Expiration of a drug patent or availability of a generic drug.

(iii) Material shortage that results in a significant price increase for the drug.

(iv) Withdrawal of a drug from the market.

(2) The alternative payment amount established under section 1847A of the Act may be used to establish payment for a CAP drug if—

(i) The drug is properly assigned to a category established under the CAP; and

(ii) It is a drug for which a HCPCS code must be established.

(d) *Adjustments.* There is an established process for adjustments to payments to account for drugs that were billed, but which were not administered.

(e) *Resupply of participating CAP physician drug inventory.* A participating CAP physician may acquire drugs under the CAP to resupply his or her private inventory if all of the following requirements are met:

(1) The drugs were required immediately.

(2) The participating CAP physician could not have anticipated the need for the drugs.

(3) The approved CAP vendor could not have delivered the drugs in a timely manner. For purposes of this section, timely manner means delivery within the emergency delivery timeframe, as defined in § 414.902.

(4) The participating CAP physician administered the drugs in an emergency situation, as defined in § 414.902.

(f) *Substitution of CAP drugs.* An approved CAP vendor may agree to furnish more than one CAP drug (defined at the NDC level) for a HCPCS code. Payment is based on a bid price defined by the HCPCS code and the unit of measure for the HCPCS code. Substitution of a different NDC within the HCPCS code for the NDC currently furnished by the approved CAP vendor can occur in the following situations:

(1) On an occasional basis, if the approved CAP vendor is willing to accept

the payment amount that was established for the original NDC within a HCPCS code under the CAP, and the participating CAP physician approves the substitution; or

(2) For an extended period of time (more than 2 weeks), if the approved CAP vendor identifies the replacement product, the designated carrier's medical director approves the long-term substitution on behalf of CMS, and all participating CAP physicians who have selected the approved CAP vendor are notified of the change. In the case of such long-term substitution, payment is based on the price established in accordance with § 414.906(c).

[70 FR 39094, July 6, 2005]

§ 414.908 Competitive acquisition program.

(a) Participating CAP *physician selection of an approved CAP vendor*. (1) CMS provides the participating CAP physician with a process for the selection of an approved CAP vendor on an annual basis, with exceptions as specified in § 414.908(a)(2). Participating CAP physicians will also receive information about the CAP in the enrollment process for Medicare participation set forth in section 1842(h) of the Act.

(2) A participating CAP physician may select an approved CAP vendor outside the annual selection process or opt out of the CAP for the remainder of the annual selection period when—

(i) The selected approved CAP vendor ceases participation in the CAP;

(ii) The physician leaves a group practice participating in CAP;

(iii) The participating CAP physician relocates to another competitive acquisition area; or

(iv) For other exigent circumstances defined by CMS.

(3) The physician participating in the CAP—

(i) Elects to use an approved CAP vendor for the drug category and area as set forth in § 414.908(b);

(ii) Completes and signs the CAP election agreement;

(iii) Submits a written prescription order to the approved CAP vendor with complete patient information for patients new to the approved CAP vendor or when information changes. Abbreviated information may be sent on all subsequent orders for a patient for which the approved CAP vendor has previously received complete information and that has no changes to the original information. Prescription orders may be initiated by telephone, with a follow-up written order provided within 8 hours for routine deliveries and immediately for emergency deliveries;

(iv) Does not receive payment for the CAP drug;

(v) Except where applicable State pharmacy law prohibits it, provides the following information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3):

(A) Date of order.

(B) Beneficiary name, address, and phone number.

(C) Physician identifying information:

Name, practice location/shipping address, group practice information (if applicable), PIN, and UPIN.

(D) Drug name.

(E) Strength.

(F) Quantity ordered.

(G) Dose.

(H) Frequency/instructions.

(I) Anticipated date of administration.

(J) Beneficiary Medicare information/Health insurance (HIC) number.

(K) Supplementary insurance information (if applicable).

(L) Medicaid information (if applicable).

(M) Additional patient information: date of birth, allergies, height/weight, ICD–9.

(vi) Notifies the approved CAP vendor when a drug is not administered or a smaller amount was administered than was originally ordered. The participating CAP physician and the approved CAP vendor agree on how to handle the unused CAP drug. If it is agreed that the participating CAP physician will maintain the CAP drug in his inventory for administration at a later date, the participating CAP physician submits a new prescription order at that time. This prescription order specifies that the CAP drug is being obtained from the participating CAP physician's CAP inventory and shipment should not occur;

(vii) Maintains a separate electronic or paper inventory for each CAP drug obtained;

(viii) Agrees to file the Medicare claim within 14 calendar days of the date of drug administration;

(ix) Agrees to submit an appeal accompanied by all required documentation (such as medical records or a certification) necessary to support payment if the participating CAP physician's drug administration claim for a CAP drug is denied;

(x) Agrees not to transport CAP drugs from one practice location (place of service) to another location;

(xi) Agrees to provide the CMS-developed CAP fact sheet to beneficiaries; and

(xii) May receive payment under the ASP system when medical necessity requires a certain brand or formulation of a drug that the approved CAP vendor has not been contracted to furnish under the CAP.

(4) Physician group practices. If a physician group practice using a group billing number(s) elects to participate in the CAP, all physicians in the group are considered to be participating CAP physicians when using the group's billing number(s).

(5) *Additional opt out provision.* In addition to the circumstances listed in § 414.908(a)(2), if the approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(h) have been met, the physician can withdraw from CAP for the remainder of the year immediately upon notice to CMS and the approved CAP vendor.

(b) *Program requirements.* (1) CMS selects approved CAP vendors through a competition among entities based on the following:

(i) Submission of the bid prices using the OMB-approved Vendor Application and Bid Form for CAP drugs within the category and competitive acquisition area that—

(A) Places the vendor among the qualified bidders with the lowest five composite bids; and

(B) Does not exceed the weighted payment amount established under section 1847A of the Act across all drugs in that category.

(ii) Ability to ensure product integrity.

(iii) Customer service/Grievance process.

(iv) At least 3 years experience in furnishing Part B injectable drugs.

(v) Financial performance and solvency.

(vi) Record of integrity and the implementation of internal integrity measures.

(vii) Internal financial controls.

(viii) Acquisition of all CAP drugs directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer.

(ix) Maintenance of appropriate licensure to supply CAP drugs in States in which they are supplying CAP drugs.

(x) Cost-sharing assistance as described in § 414.914(g).

(xi) Other factors as determined by CMS.

(2) Approved CAP vendors must also meet the contract requirements under § 414.914.

(c) *Additional considerations.* CMS may refuse to award a contract or terminate an approved CAP vendor contract based upon the following:

(1) Suspension or revocation by the Federal or State government of the entity's license for distribution of drugs, including controlled substances.

(2) Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs. These considerations are in addition to CMS' ability to terminate the approved CAP vendor for cause as specified in § 414.914(a).

(3) Past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

(d) *Multiple source drugs.* In the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one CAP drug within each billing and payment code within each category for each competitive acquisition area.

(e) *Multiple contracts for a category and area.* The number of bidding qualified entities that are awarded a contract for a given category and area may be limited to no fewer than two.

[70 FR 39094, July 6, 2005]

§414.910 Bidding process.

(a) Entities may bid to furnish CAP drugs in all competitive acquisition areas of the United States, or one or more specific competitive acquisition areas.

(b) The amount of the bid for any CAP drug for a specific competitive acquisition area must be uniform for all portions of that competitive acquisition area.

(c) A submitted bid price must include the following:

(1) All costs related to the delivery of the drug to the participating CAP physician.

(2) The costs of dispensing (including shipping) of the drug and management fees. The costs related to the administration of the drug or wastage, spillage, or spoilage may not be included.

[70 FR 39095, July 6, 2005]

§414.912 Conflicts of interest

(a) Approved CAP vendors and applicants that bid to participate in the CAP are subject to the following:

(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance, found under FAR subpart 9.5.

(2) Those requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act.

(b) *Post-award conflicts of interest.* Approved CAP vendors must have a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest between the approved CAP vendor and any entity, including the Federal Government, with whom it does business. The code of conduct which is submitted as part of the application must—

(1) State the need for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for conflicts of interest; and

(2) State the approved CAP vendor's expectations for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for detecting, preventing, and resolving conflicts of interest.

[70 FR 39094, July 6, 2005]

§414.914 Terms of contract.

(a) The contract between CMS and the approved CAP vendor will be for a term of 3 years, unless terminated or suspended earlier as provided in this section or provided in §414.917. The contract may be terminated—

(1) By CMS for default if the approved CAP vendor violates any term of the contract; or

(2) In the absence of a contract violation, by either CMS or the approved CAP vendor, if the terminating party notifies the other party by June 30 for an effective date of termination of December 31 of that year.

(b) The contract will provide for a code of conduct for the approved CAP vendor that includes standards relating to conflicts of interest standards as set forth at §414.912.

(c) The approved CAP vendor will have and implement a compliance plan that contains policies and procedures that control program fraud, waste, and abuse, and consists of the following minimum elements:

(1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State laws, regulations, and guidance, including, but not limited to, the Prescription Drug Marketing Act (PDMA), the physician self-referral (''Stark'') prohibition, the Anti-Kickback statute and the False Claims Act.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education of the compliance officer and organization employees, contractors, agents, and directors.

(4) Enforcement of standards through well publicized disciplinary guidelines.

(5) Procedures for effective internal monitoring and auditing.

(6) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as an approved CAP vendor.

(i) If the approved CAP vendor discovers evidence of misconduct related

to payment or delivery of drugs or biologicals under the contract, it will conduct a timely and reasonable inquiry into that conduct.

(ii) The approved CAP vendor will conduct appropriate corrective actions including, but not limited to, repayment of overpayments and disciplinary actions against responsible individuals, in response to potential violations referenced at paragraph (c)(6)(i) of this section.

(7) Procedures to voluntarily self-report potential fraud or misconduct related to the CAP to the appropriate government agency.

(d) The contract must provide for disclosure of the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, not to exceed quarterly.

(e) The contract must provide for appropriate adjustments as described in § 414.906(c)(1).

(f) Under the terms of the contract, the approved CAP vendor must also—

(1) Have sufficient arrangements to acquire and deliver CAP drugs within the category in the competitive acquisition area specified by the contract;

(2) Have arrangements in effect for shipment at least 5 weekdays each week of CAP drugs under the contract, including the ability to comply with the routine and emergency delivery timeframes defined in § 414.902;

(3) Have procedures in place to address and resolve complaints of participating CAP physicians and individuals and inquiries regarding shipment of CAP drugs;

(4) Have a grievance and appeals process for dispute resolution;

(5) Meet applicable licensure requirements in each State in which it supplies drugs under the CAP;

(6) Be enrolled in Medicare as a participating supplier;

(7) Comply with all applicable Federal and State laws, regulations and guidance related to the prevention of fraud and abuse;

(8) Supply CAP drugs upon receipt of a prescription order to all participating CAP physicians who have selected the approved CAP vendor, except when the conditions of § 414.914(h) are met;

(9) Ensure that subcontractors who are involved in providing services under the approved CAP contractor's CAP contract meet all requirements and comply with all laws and regulations relating to the services they provide under the CAP program. Notwithstanding any relationship the CAP vendor may have with any subcontractor, the approved CAP vendor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS;

(10) Comply with product integrity and record keeping requirements including but not limited to drug acquisition, handling, storage, shipping, drug waste, and return processes; and

(11) Comply with such other terms and conditions as CMS may specify in the CAP contract consistent with section 1847B of the Act.

(g) Under the terms of the contract, the approved CAP vendor must provide assistance to beneficiaries experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

(1) Referral to a bona fide and independent charitable organization.

(2) Implementation of a reasonable payment plan.

(3) A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of ''Remuneration'' in § 1003.101 of this title. The availability of waivers may not be advertised or be made as part of a solicitation. Approved CAP vendors may inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries will receive cost-sharing waivers.

(h) The approved CAP vendor must comply with the following procedures before it may refuse to make further shipments of CAP drugs to a participating CAP physician on behalf of a beneficiary:

(1) Subsequent to receipt of final payment by Medicare, the approved CAP vendor must bill any applicable supplemental insurance policies.

(2) If after that action is taken, a balance remains, or if there is no supplemental insurance, the approved CAP vendor may bill the beneficiary.

(3) At the time of billing, the approved CAP vendor may inform the beneficiary of any types of cost-sharing assistance that may be available consistent with the requirements of section 1128A(a)(5) of the Act and §414.914(g).

(4) If the beneficiary demonstrates a financial need, the approved CAP vendor must follow the conditions outlined in paragraph (g) of this section.

(5) If after 45 days from the postmark date of the approved CAP vendor's bill to the beneficiary, the beneficiary's cost sharing obligation remains unpaid, the approved CAP vendor may refuse further shipments to the participating CAP physician for that beneficiary; however, if the beneficiary has requested cost-sharing assistance within the 45-day period, the provisions of paragraph (6), (7), or (8), as applicable, apply.

(6) If the approved CAP vendor implements a reasonable payment plan, as specified in §414.914(g)(2), the approved CAP vendor must continue to ship CAP drugs for the beneficiary, as long as the beneficiary remains in compliance with the payment plan and makes an initial payment under the plan within 15 days after the postmark date of the approved CAP vendor's written notice to the beneficiary offering the payment plan.

(7) If the approved CAP vendor has waived the cost-sharing obligations in accordance with section 1128A of the Act and §414.914(g)(3), the approved CAP vendor may not refuse to ship drugs for that beneficiary.

(8) If the approved CAP vendor refers the beneficiary to a bona fide and independent charity in accordance with §414.914(g)(1), the approved CAP vendor may refuse to ship drugs if the past due balance is not paid 15 days after the postmark date of the approved CAP vendor's written notice to the beneficiary containing the referral for cost-sharing assistance.

(9) The approved CAP vendor may refuse to make further shipments to that participating CAP physician on behalf of the beneficiary for the lesser of the end of the calendar year or until the beneficiary's balance is paid in full.

[70 FR 39096, July 6, 2005]

§414.916 Dispute resolution for vendors and beneficiaries.

(a) *General rule.* Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process delivered by the designated carrier, and a reconsideration process provided by CMS.

(b) *Dispute resolution.* (1) When an approved CAP vendor is not paid on claims submitted to the designated carrier, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician on his or her agreement to file a clean claim and pursue an administrative appeal in accordance with subpart H of part 405 of this chapter. If problems persist, the approved CAP vendor may ask the designated carrier to—

(i) Review the participating CAP physician's performance; and

(ii) Potentially recommend to CMS that CMS suspend the participating CAP physician's CAP election agreement.

(2) The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the participating CAP physician has been filing his or her CAP drug administration claims in accordance with the requirements for physician participation in the CAP as set forth in §414.908(a)(3). The recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and gather relevant additional information from the participating CAP physician before deciding whether to suspend the participating CAP physician's CAP election agreement. A suspension commencing before October 1 will conclude on December 31 of the same year. A

suspension commencing on or after October 1 will conclude on December 31 of the next year.

(4) The participating CAP physician may appeal that suspension by requesting a reconsideration of CMS' decision. The reconsideration will address whether the participating CAP physician's denied claims and appeals were the result of the participating CAP physician's failure to participate in accordance with the requirements of § 414.908(a)(3).

(c) *Reconsideration.* (1) *Right to reconsideration.* A participating CAP physician dissatisfied with a determination that his or her CAP election agreement has been suspended by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS reconsiders any determination to suspend a participating CAP physician's election agreement if the participating CAP physician files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* A participating CAP physician who is dissatisfied with a CMS decision to suspend his or her CAP election agreement may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the participating CAP physician of CMS' decision to suspend his or her CAP election agreement. From the date of receipt of the decision letter until the day the reconsideration determination is final, the ASP payment methodology under section 1847A of the Act applies to the physician.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the participating CAP physician disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the participating CAP physician's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from approved CAP vendors, local carriers, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* A participating CAP physician may withdraw his or her request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the participating CAP physician the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the participating CAP physician the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate a participating CAP physician's CAP election agreement.

(7) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the participating CAP physician requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carrier;

(*4*) Representatives from the approved CAP vendor; and

(*5*) Legal counsel.

(B) The hearing is conducted by the hearing officer who receives relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena

the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer presents the findings and recommendations to the participating CAP physician who requested the reconsideration. If the hearing officer decides to conduct an in-person or telephone hearing, the hearing officer will send a hearing notice to the participating CAP physician within 10 days of receipt of the hearing request, and the findings and recommendations are due to the participating CAP physician within 30 days of the hearing's conclusion.

(ii) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the director of the CMS Center for Medicare Management or his or her designee chooses to review that decision within 30 days. If the decision is favorable to the participating CAP physician, then the participating CAP physician may resume his or her participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the participating CAP physician.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official issues a final reconsideration determination to the participating CAP physician on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final. If the final decision is unfavorable to the participating CAP physician, then the participating CAP physician's CAP election agreement is terminated.

(d) The approved CAP vendor may not charge the beneficiary for the full drug coinsurance amount if the designated contractor did not pay the approved CAP vendor in full, unless a properly executed advance beneficiary notice is in place. When a beneficiary receives an inappropriate coinsurance bill, the beneficiary may participate in the approved CAP vendor's grievance process to request correction of the approved CAP vendor's file. If the beneficiary is dissatisfied with the result of the approved CAP vendor's grievance process, the beneficiary may request intervention from the designated carrier. This is in addition to, rather than in place of, any other beneficiary appeal rights. The designated carrier will first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file.

[70 FR 39097, July 6, 2005]

§414.917 Dispute resolution and process for suspension or termination of approved CAP contract.

(a) *General rule.* If a participating CAP physician finds an approved CAP vendor's service, or the quality of a CAP drug supplied by the approved CAP vendor to be unsatisfactory, then the physician may address the issue first through the approved CAP vendor's grievance process, and second through an alternative dispute resolution process administered by the designated carrier and CMS. If CMS suspends an approved CAP vendor's CAP contract for noncompliance or terminates the CAP contract in accordance with §414.914(a), the approved CAP vendor may request a reconsideration in accordance with paragraph (c) of this section.

(b) *Dispute resolution.* (1) When a participating CAP physician is dissatisfied with an approved CAP vendor's service or the quality of a CAP drug supplied by the approved CAP vendor, then the participating CAP physician may use the approved CAP vendor's grievance process. If the service or quality issues are not resolved through the grievance process to the physician's satisfaction, then the participating CAP physician may ask the designated carrier to—

(i) Review the approved CAP vendor's performance; and

(ii) Potentially recommend termination of the approved CAP vendor's CAP contract.

(2) *Responsibility of the designated carrier.* The designated carrier—

(i) Gathers information from the local carrier, the participating CAP

physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. This recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and, gather relevant additional information from the approved CAP vendor, the participating CAP physician, the local carrier, and the beneficiary before deciding whether to terminate the approved CAP vendor's CAP contract.

(4) The approved CAP vendor may appeal that termination by requesting a reconsideration. A determination must be made as to whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract.

(c) *Reconsideration.* (1) *Right to reconsideration.* An approved CAP vendor dissatisfied with a determination that its CAP contract has been suspended or terminated by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS will reconsider any determination to suspend or terminate an approved CAP vendor's contract if the approved CAP vendor files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* An approved CAP vendor that is dissatisfied with a CMS decision to suspend or terminate its CAP contract may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the approved CAP vendor of the suspension or termination of its CAP contract.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the approved CAP vendor disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the approved CAP vendor's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from participating CAP physicians, the local carrier, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* An approved CAP vendor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the approved CAP vendor the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the Director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the approved CAP vendor the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate the approved CAP vendor's CAP contract.

(7) *Informal hearing procedures.* (i) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the approved CAP vendor requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carriers and the designated carrier;

(*4*) The participating CAP physician who requested the suspension, if any; and

(*5*) Legal counsel.

(B) The hearing will be conducted by the hearing officer, who will receive relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in the paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer will present the findings and recommendations to the approved CAP vendor that requested the reconsideration. If the hearing officer conducts a hearing in person or by phone, the hearing officer will send a hearing notice to the approved CAP vendor within 10 days of receipt of the hearing request, and the findings and recommendations are due to the approved CAP vendor within 30 days from of the hearing's conclusion.

(ii) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the Director of the CMS Center for Medicare Management or his or her designee (CMS official) chooses to review that decision within 30 days. If the decision is favorable to the approved CAP vendor, then the approved CAP vendor may resume participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the approved CAP vendor.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official will issue a final reconsideration determination to the approved CAP vendor on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final.

[70 FR 39098, July 6, 2005]

§414.918 Assignment.

Payment for a CAP drug may be made only on an assignment-related basis.

[70 FR 39099, July 6, 2005]

§414.920 Judicial review.

The following areas under the CAP are not subject to administrative or judicial review:

(a) The establishment of payment amounts.

(b) The awarding of vendor contracts.

(c) The establishment of competitive acquisition areas.

(d) The selection of CAP drugs.

(e) The bidding structure.

(f) The number of vendors selected.

[70 FR 39099, July 6, 2005]

Subpart L—Supplying and Dispensing Fees

§414.1000 Purpose.

This subpart implements section 1842(o)(2) and section 1842(o)(6) of the Act, as added by section 303(e)(2) of the MMA, by specifying a supplying fee for drugs and biologicals covered under Part B of Title XVIII of the Act that are described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

[69 FR 66425, Nov. 15, 2004]

§414.1001 Basis of payment.

(a) A supplying fee of $24 shall be paid to a pharmacy for each supplied prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

(b) A supplying fee of $50 is paid to a pharmacy for the initial supplied prescription of drugs and biologicals described in sections 1861(s)(2)(J) of the Act provided to a patient during the first month following a transplant.

(c) During 2005, a dispensing fee of $57 is paid to a supplier for each dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(d) During 2005, a dispensing fee of $80 is paid to a supplier for each dispensed 90-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of

partial shipments of that 90-day supply.

[69 FR 66425, Nov. 15, 2004]

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

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415.208 Services of moonlighting residents.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 60 FR 63178, Dec. 8, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 415.1 Basis and scope.

(a) *Basis*. This part is based on the provisions of the following sections of the Act: Section 1848 establishes a fee schedule for payment for physician services. Section 1861(q) specifies what is included in the term ''physician services'' covered under Medicare. Section 1862(a)(14) sets forth the exclusion of nonphysician services furnished to hospital patients under Part B of Medicare. Section 1886(d)(5)(B) provides for a payment adjustment under the prospective payment system for the operating costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1983, to account for the indirect costs of medical education. Section 1886(h) establishes the methodology for Medicare payment of the cost of direct GME activities.

(b) *Scope*. This part sets forth rules for fiscal intermediary payments to providers for physician services, Part B carrier payments for physician services to beneficiaries in providers, physician services in teaching settings, and services of residents.

Subpart B—Fiscal Intermediary Payments to Providers for Physician Services

§ 415.50 Scope.

This subpart sets forth rules for payment by fiscal intermediaries to providers for services furnished by physicians. Payment for covered services is made either under the prospective payment system (PPS) to PPS-participating providers in accordance with part 412 of this chapter or under the reasonable cost method to non-PPS participating providers in accordance with part 413 of this chapter.

§ 415.55 General payment rules.

(a) *Allowable costs*. Except as specified otherwise in §§ 413.102 of this chapter (concerning compensation of owners), 415.60 (concerning allocation of physician compensation costs), and 415.162 (concerning payment for physician services furnished to beneficiaries in teaching hospitals), costs a provider incurs for services of physicians are allowable only if the following conditions are met:

(1) The services do not meet the conditions in § 415.102(a) regarding fee schedule payment for services of physicians to a beneficiary in a provider.

(2) The services include a surgeon's supervision of services of a qualified anesthetist, but do not include physician availability services, except for reasonable availability services furnished for emergency rooms and the services of standby surgical team physicians.

(3) The provider has incurred a cost for salary or other compensation it furnished the physician for the services.

(4) The costs incurred by the provider for the services meet the requirements in § 413.9 of this chapter regarding costs related to patient care.

(5) The costs do not include supervision of interns and residents unless the provider elects reasonable cost payment as specified in § 415.160, or any other costs incurred in connection with an approved GME program that are payable under §§ 413.75 through 413.83 of this chapter.

(b) *Allocation of allowable costs*. The provider must follow the rules in § 415.60 regarding allocation of physician compensation costs to determine its costs of services.

(c) *Limits on allowable costs*. The intermediary must apply the limits on compensation set forth in § 415.70 to determine its payments to a provider for the costs of services.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.60 Allocation of physician compensation costs.

(a) *Definition*. For purposes of this subpart, *physician compensation costs* means monetary payments, fringe benefits, deferred compensation, and any other items of value (excluding office space or billing and collection services) that a provider or other organization furnishes a physician in return for the physician services. Other organizations are entities related to the provider within the meaning of § 413.17 of this chapter or entities that furnish services for the provider under arrangements within the meaning of the Act.

(b) *General rule*. Except as provided in paragraph (d) of this section, each provider that incurs physician compensation costs must allocate those costs, in proportion to the percentage of total time that is spent in furnishing each category of services, among—

(1) Physician services to the provider (as described in § 415.55);

(2) Physician services to patients (as described in § 415.102); and

(3) Activities of the physician, such as funded research, that are not paid under either Part A or Part B of Medicare.

(c) *Allowable physician compensation costs*. Only costs allocated to payable physician services to the provider (as described in § 415.55) are allowable costs to the provider under this subpart.

(d) *Allocation of all compensation to services to the provider*. Generally, the total physician compensation received by a physician is allocated among all services furnished by the physician, unless—

(1) The provider certifies that the compensation is attributable solely to the physician services furnished to the provider; and

(2) The physician bills all patients for the physician services he or she furnishes to them and personally receives

the payment from or on behalf of the patients. If returned directly or indirectly to the provider or an organization related to the provider within the meaning of § 413.17 of this chapter, these payments are not compensation for physician services furnished to the provider.

(e) *Assumed allocation of all compensation to beneficiary services.* If the provider and physician agree to accept the assumed allocation of all the physician services to direct services to beneficiaries as described under § 415.102(a), CMS does not require a written allocation agreement between the physician and the provider.

(f) *Determination and payment of allowable physician compensation costs.* (1) Except as provided under paragraph (e) of this section, the intermediary pays the provider for these costs only if—

(i) The provider submits to the intermediary a written allocation agreement between the provider and the physician that specifies the respective amounts of time the physician spends in furnishing physician services to the provider, physician services to patients, and services that are not payable under either Part A or Part B of Medicare; and

(ii) The compensation is reasonable in terms of the time devoted to these services.

(2) In the absence of a written allocation agreement, the intermediary assumes, for purposes of determining reasonable costs of the provider, that 100 percent of the physician compensation cost is allocated to services to beneficiaries as specified in paragraph (b)(2) of this section.

(g) *Recordkeeping requirements.* Except for services furnished in accordance with the assumed allocation under paragraph (e) of this section, each provider that claims payment for services of physicians under this subpart must meet all of the following requirements:

(1) Maintain the time records or other information it used to allocate physician compensation in a form that permits the information to be validated by the intermediary or the carrier.

(2) Report the information on which the physician compensation allocation is based to the intermediary or the carrier on an annual basis and promptly notify the intermediary or carrier of any revisions to the compensation allocation.

(3) Retain each physician compensation allocation, and the information on which it is based, for at least 4 years after the end of each cost reporting period to which the allocation applies.

§ 415.70 Limits on compensation for physician services in providers.

(a) *Principle and scope.* (1) Except as provided in paragraphs (a)(2) and (a)(3) of this section, CMS establishes reasonable compensation equivalency limits on the amount of compensation paid to physicians by providers. These limits are applied to a provider's costs incurred in compensating physicians for services to the provider, as described in § 415.55(a).

(2) Limits established under this section do not apply to costs of physician compensation attributable to furnishing inpatient hospital services that are paid for under the prospective payment system implemented under part 412 of this chapter or to costs of physician compensation attributable to approved GME programs that are payable under §§ 413.75 through 413.83 of this chapter.

(3) Compensation that a physician receives for activities that may not be paid for under either Part A or Part B of Medicare is not considered in applying these limits.

(b) *Methodology for establishing limits.* CMS establishes a methodology for determining annual reasonable compensation equivalency limits and, to the extent possible, considers average physician incomes by specialty and type of location using the best available data.

(c) *Application of limits.* If the level of compensation exceeds the limits established under paragraph (b) of this section, Medicare payment is based on the level established by the limits.

(d) *Adjustment of the limits.* The intermediary may adjust limits established under paragraph (b) of this section to account for costs incurred by the physician or the provider related to malpractice insurance, professional memberships, and continuing medical education.

(1) For the costs of membership in professional societies and continuing medical education, the intermediary may adjust the limit by the lesser of—

(i) The actual cost incurred by the provider or the physician for these activities; or

(ii) Five percent of the appropriate limit.

(2) For the cost of malpractice expenses incurred by either the provider or the physician, the intermediary may adjust the reasonable compensation equivalency limit by the cost of the malpractice insurance expense related to the physician service furnished to patients in providers.

(e) *Exception to limits.* An intermediary may grant a provider an exception to the limits established under paragraph (b) of this section only if the provider can demonstrate to the intermediary that it is unable to recruit or maintain an adequate number of physicians at a compensation level within these limits.

(f) *Notification of changes in methodologies and payment limits.* (1) Before the start of a cost reporting period to which limits established under this section will be applied, CMS publishes a notice in the FEDERAL REGISTER that sets forth the amount of the limits and explains how it calculated the limits.

(2) If CMS proposes to revise the methodology for establishing payment limits under this section, CMS publishes a notice, with opportunity for public comment, in the FEDERAL REGISTER. The notice explains the proposed basis and methodology for setting limits, specifies the limits that would result, and states the date of implementation of the limits.

(3) If CMS updates limits by applying the most recent economic index data without revising the limit methodology, CMS publishes the revised limits in a notice in the FEDERAL REGISTER without prior publication of a proposal or public comment period.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

Subpart C—Part B Carrier Payments for Physician Services to Beneficiaries in Providers

§415.100 Scope.

This subpart implements section 1887(a)(1)(A) of the Act by providing general conditions that must be met in order for services furnished by physicians to beneficiaries in providers to be paid for on the basis of the physician fee schedule under part 414 of this chapter. Section 415.102 sets forth the conditions for fee schedule payment for physician services to beneficiaries in providers. Section 415.105 sets forth general requirements for determining the amounts of payment for services that meet the conditions of this section. Sections 415.120 and 415.130 set forth additional conditions for payment for physician services in the specialties of radiology and pathology (laboratory services).

§415.102 Conditions for fee schedule payment for physician services to beneficiaries in providers.

(a) *General rule.* If the physician furnishes services to beneficiaries in providers, the carrier pays on a fee schedule basis provided the following requirements are met:

(1) The services are personally furnished for an individual beneficiary by a physician.

(2) The services contribute directly to the diagnosis or treatment of an individual beneficiary.

(3) The services ordinarily require performance by a physician.

(4) In the case of radiology or laboratory services, the additional requirements in §415.120 or §415.130, respectively, are met.

(b) *Exception.* If a physician furnishes services in a provider that do not meet the requirements in paragraph (a) of this section, but are related to beneficiary care furnished by the provider, the intermediary pays for those services, if otherwise covered. The intermediary follows the rules in §§415.55 and 415.60 for payment on the basis of reasonable cost or PPS, as appropriate.

(c) *Effect of billing charges for physician services to a provider.*

(1) If a physician furnishes services that may be paid under the reasonable

cost rules in § 415.55 or § 415.60, and paid by the intermediary, or would be paid under those rules except for the PPS rules in part 412 of this chapter, and under the payment rules for GME established by §§ 413.75 through 413.83 of this chapter, neither the provider nor the physician may seek payment from the carrier, beneficiary, or another insurer.

(2) If a physician furnishes services to an individual beneficiary that do not meet the applicable conditions in §§ 415.120 (concerning conditions for payment for radiology services) and 415.130 (concerning conditions for payment for physician pathology services), the carrier does not pay on a fee schedule basis.

(3) If the physician, the provider, or another entity bills the carrier or the beneficiary or another insurer for physician services furnished to the provider, as described in § 415.55(a), CMS considers the provider to which the services are furnished to have violated its provider participation agreement, and may terminate that agreement. See part 489 of this chapter for rules governing provider agreements.

(d) *Effect of physician assumption of operating costs.* If a physician or other entity enters into an agreement (such as a lease or concession) with a provider, and the physician (or entity) assumes some or all of the operating costs of the provider department in which the physician furnishes physician services, the following rules apply:

(1) If the conditions set forth in paragraph (a) of this section are met, the carrier pays for the physician services under the physician fee schedule in part 414 of this chapter.

(2) To the extent the provider incurs a cost payable on a reasonable cost basis under part 413 of this chapter, the intermediary pays the provider on a reasonable cost basis for the costs associated with producing these services, including overhead, supplies, equipment costs, and services furnished by nonphysician personnel.

(3) The physician (or other entity) is treated as being related to the provider within the meaning of § 413.17 of this chapter (concerning cost to related organizations).

(4) The physician (or other entity) must make its books and records available to the provider and the intermediary as necessary to verify the nature and extent of the costs of the services furnished by the physician (or other entity).

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.105 Amounts of payment for physician services to beneficiaries in providers.

(a) *General rule.* The carrier determines amounts of payment for physician services to beneficiaries in providers in accordance with the general rules governing the physician fee schedule payment in part 414 of this chapter, except as provided in paragraph (b) of this section.

(b) *Application in certain settings*—(1) *Teaching hospitals.* The carrier applies the rules in subpart D of this part (concerning physician services in teaching settings), in addition to those in this section, in determining whether fee schedule payment should be made for physician services to individual beneficiaries in a teaching hospital.

(2) *Hospital-based ESRD facilities.* The carrier applies §§ 414.310 through 414.314 of this chapter, which set forth determination of reasonable charges under the ESRD program, to determine the amount of payment for physician services furnished to individual beneficiaries in a hospital-based ESRD facility approved under part 405 subpart U.

§ 415.110 Conditions for payment: Medically directed anesthesia services.

(a) *General payment rule.* Medicare pays for the physician's medical direction of anesthesia services for one service or two through four concurrent anesthesia services furnished after December 31, 1998, only if each of the services meets the condition in § 415.102(a) and the following additional conditions:

(1) For each patient, the physician—

(i) Performs a pre-anesthetic examination and evaluation;

(ii) Prescribes the anesthesia plan;

(iii) Personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;

(iv) Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual as defined in operating instructions;

(v) Monitors the course of anesthesia administration at frequent intervals;

(vi) Remains physically present and available for immediate diagnosis and treatment of emergencies; and

(vii) Provides indicated post-anesthesia care.

(2) The physician directs no more than four anesthesia services concurrently and does not perform any other services while he or she is directing the single or concurrent services so that one or more of the conditions in paragraph (a)(1) of this section are not violated.

(3) If the physician personally performs the anesthesia service, the payment rules in §414.46(c) of this chapter apply (Physician personally performs the anesthesia procedure).

(b) *Medical documentation*. The physician alone inclusively documents in the patient's medical record that the conditions set forth in paragraph (a)(1) of this section have been satisfied, specifically documenting that he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable.

[63 FR 58912, Nov. 2, 1998]

§415.120 Conditions for payment: Radiology services.

(a) *Services to beneficiaries*. The carrier pays for radiology services furnished by a physician to a beneficiary on a fee schedule basis only if the services meet the conditions for fee schedule payment in §415.102(a) and are identifiable, direct, and discrete diagnostic or therapeutic services furnished to an individual beneficiary, such as interpretation of x-ray plates, angiograms, myelograms, pyelograms, or ultrasound procedures. The carrier pays for interpretations only if there is a written report prepared for inclusion in the patient's medical record maintained by the hospital.

(b) *Services to providers*. The carrier does not pay on a fee schedule basis for physician services to the provider (for example, administrative or supervisory services) or for provider services needed to produce the x-ray films or other items that are interpreted by the radiologist. However, the intermediary pays the provider for these services in accordance with §415.55 for provider costs; §415.102(d)(2) for costs incurred by a physician, such as under a lease or concession agreement; or part 412 of this chapter for payment under PPS.

§415.130 Conditions for payment: Physician pathology services.

(a) *Definitions*. The following definitions are used in this section.

(1) *Covered hospital* means, with respect to an inpatient or an outpatient, a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the technical component of physician pathology services to fee-for-service Medicare beneficiaries who were hospital inpatients or outpatients, and submitted claims for payment for this technical component directly to a Medicare carrier.

(2) *Fee-for-service Medicare beneficiaries* means those beneficiaries who are entitled to benefits under Part A or are enrolled under Part B of Title XVIII of the Act or both and are not enrolled in any of the following:

(i) A Medicare+Choice plan under Part C of Title XVIII of the Act.

(ii) A plan offered by an eligible organization under section 1876 of the Act;

(iii) A program of all-inclusive care for the elderly (PACE) under 1894 of the Act; or

(iv) A social health maintenance organization (SHMO) demonstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987.

(b) *Physician pathology services*. The carrier pays for pathology services furnished by a physician to an individual beneficiary on a fee schedule basis only if the services meet the conditions for payment in §415.102(a) and are one of the following services:

(1) Surgical pathology services.

(2) Specific cytopathology, hematology, and blood banking services that have been identified to require performance by a physician and are listed in program operating instructions.

(3) Clinical consultation services that meet the requirements in paragraph (c) of this section.

(4) Clinical laboratory interpretative services that meet the requirements of paragraphs (c)(1), (c)(3), and (c)(4) of this section and that are specifically listed in program operating instructions.

(c) *Clinical consultation services*. For purposes of this section, clinical consultation services must meet the following requirements:

(1) Be requested by the beneficiary's attending physician.

(2) Relate to a test result that lies outside the clinically significant normal or expected range in view of the condition of the beneficiary.

(3) Result in a written narrative report included in the beneficiary's medical record.

(4) Require the exercise of medical judgment by the consultant physician.

(d) *Physician pathology services furnished by an independent laboratory*. The technical component of physician pathology services furnished by an independent laboratory to a hospital inpatient or outpatient before January 1, 2001 may be paid to the laboratory on a fee schedule basis. After December 31, 2000 but before January 1, 2003, if an independent laboratory furnishes the technical component of a physician pathology service to a fee-for-service Medicare beneficiary who is an inpatient or outpatient of a covered hospital, the carrier will treat the technical component as a service for which payment will be made to the laboratory under the physician fee schedule. For these two years the service will not be treated as an inpatient hospital service for which payment is made to the hospital under section 1886(d) of the Act or as an outpatient hospital service for which payment is made to the hospital under section 1833(t) of the Act. After December 31, 2002, the technical component for physician pathology services furnished by an independent laboratory to a hospital inpatient or outpatient is paid only to the hospital.

[60 FR 63178, Dec. 8, 1995, as amended at 64 FR 59442, Nov. 2, 1999; 66 FR 55332, Nov. 1, 2001]

Subpart D—Physician Services in Teaching Settings

§ 415.150 Scope.

This subpart sets forth the rules governing payment for the services of physicians in teaching settings and the criteria for determining whether the payments are made as one of the following:

(a) Services to the hospital under the reasonable cost election in §§ 415.160 through 415.164.

(b) Provider services through the direct GME payment mechanism in §§ 413.75 through 413.83 of this chapter.

(c) Physician services to beneficiaries under the physician fee schedule as set forth in part 414 of this chapter.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.152 Definitions.

As used in this subpart—

Approved graduate medical education (GME) program means one of the following:

(1) A residency program approved by the Accreditation Council for Graduate Medical Education of the American Medical Association, by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, by the Commission on Dental Accreditation of the American Dental Association, or by the Council on Podiatric Medicine Education of the American Podiatric Medical Association.

(2) A program otherwise recognized as an ''approved medical residency program'' under § 413.75(b) of this chapter.

Direct medical and surgical services means services to individual beneficiaries that are either personally furnished by a physician or furnished by a resident under the supervision of a physician in a teaching hospital making the cost election described in §§ 415.160 through 415.162.

Nonprovider setting means a setting other than a hospital, skilled nursing

facility, home health agency, or comprehensive outpatient rehabilitation facility in which residents furnish services. These include, but are not limited to, family practice or multispecialty clinics and physician offices.

Resident means one of the following:

(1) An individual who participates in an approved GME program, including programs in osteopathy, dentistry, and podiatry.

(2) A physician who is not in an approved GME program, but who is authorized to practice only in a hospital, for example, individuals with temporary or restricted licenses, or unlicensed graduates of foreign medical schools. For purposes of this subpart, the term *resident* is synonymous with the terms *intern* and *fellow*.

Teaching hospital means a hospital engaged in an approved GME residency program in medicine, osteopathy, dentistry, or podiatry.

Teaching physician means a physician (other than another resident) who involves residents in the care of his or her patients.

Teaching setting means any provider, hospital-based provider, or nonprovider settings in which Medicare payment for the services of residents is made under the direct GME payment provisions of §§413.75 through 413.83, or on a reasonable-cost basis under the provisions of §409.26 or §409.40(f) for resident services furnished in skilled nursing facilities or home health agencies, respectively.

[60 FR 63178, Dec. 8, 1995, as amended at 61 FR 59554, Nov. 22, 1996; 63 FR 26359, May 12, 1998; 70 FR 47490, Aug. 12, 2005]

§415.160 Election of reasonable cost payment for direct medical and surgical services of physicians in teaching hospitals: General provisions.

(a) *Scope*. A teaching hospital may elect to receive payment on a reasonable cost basis for the direct medical and surgical services of its physicians in lieu of fee schedule payments that might otherwise be made for these services.

(b) *Conditions*. A teaching hospital may elect to receive these payments only if—

(1) The hospital notifies its intermediary in writing of the election and meets the conditions of either paragraph (b)(2) or paragraph (b)(3) of this section;

(2) All physicians who furnish services to Medicare beneficiaries in the hospital agree not to bill charges for these services; or

(3) All physicians who furnish services to Medicare beneficiaries in the hospital are employees of the hospital and, as a condition of employment, are precluded from billing for these services.

(c) *Effect of election*. If a teaching hospital elects to receive reasonable cost payment for physician direct medical and surgical services furnished to beneficiaries—

(1) Those services and the supervision of interns and residents furnishing care to individual beneficiaries are covered as hospital services, and

(2) The intermediary pays the hospital for those services on a reasonable cost basis under the rules in §415.162. (Payment for other physician compensation costs related to approved GME programs is made as described in §413.78 of this chapter.)

(d) *Election declined*. If the teaching hospital does not make this election, payment is made—

(1) For physician services furnished to beneficiaries on a fee schedule basis as described in part 414 subject to the rules in this subpart, and

(2) For the supervision of interns and residents as described in §§413.75 through 413.83.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§415.162 Determining payment for physician services furnished to beneficiaries in teaching hospitals.

(a) *General rule*. Payments for direct medical and surgical services of physicians furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries is made by Medicare on the basis of reasonable cost if the hospital exercises the election as provided for in §415.160. If this election is made, the following occurs:

(1) Physician services furnished to beneficiaries and supervision of interns

and residents furnishing care to beneficiaries are paid on a reasonable-cost basis, as provided for in paragraph (b) of this section.

(2) Payment for certain medical school costs may be made as provided for in paragraph (c) of this section.

(3) Payments for services donated by volunteer physicians to beneficiaries are made to a fund designated by the organized medical staff of the teaching hospital or medical school as provided for in paragraph (d) of this section.

(b) *Reasonable cost of physician services and supervision of interns and residents.* (1) Physician services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries in a teaching hospital are payable as provider services on a reasonable-cost basis.

(2) For purposes of this paragraph, *reasonable cost* is defined as the direct salary paid to these physicians, plus applicable fringe benefits.

(3) The costs must be allocated to the services as provided by paragraph (j) of this section and apportioned to program beneficiaries as provided by paragraph (g) of this section.

(4) Other allowable costs incurred by the provider related to the services described in this paragraph are payable subject to the requirements applicable to all other provider services.

(c) *Reasonable costs for the services furnished by a medical school or related organization in a hospital.* An amount is payable to the hospital by CMS under the Medicare program provided that the costs would be payable if incurred directly by the hospital rather than under the arrangement. The amount must not be in excess of the reasonable costs (as defined in paragraphs (c)(1) and (c)(2) of this section) incurred by a teaching hospital for services furnished by a medical school or organization as described in § 413.17 of this chapter for certain costs to the medical school (or a related organization) in furnishing services in the hospital.

(1) *Reasonable costs of physician services.* (i) *When the medical school and the hospital are related organizations.* If the medical school (or organization related to the medical school) and the hospital are related by common ownership or control as described in § 413.17 of this chapter—

(A) The costs of these services are allowable costs to the hospital under the provisions of § 413.17 of this chapter; and

(B) The reimbursable costs to the hospital are determined under the provisions of this section in the same manner as the costs incurred for physicians on the hospital staff and without regard to payments made to the medical school by the hospital.

(ii) *When the medical school and the hospital are not related organizations.* (A) If the medical school and the hospital are not related organizations under the provisions of § 413.17 of this chapter and the hospital makes payment to the medical school for the costs of those services furnished to all patients, payment is made by Medicare to the hospital for the reasonable cost incurred by the hospital for its payments to the medical school for services furnished to beneficiaries.

(B) Costs incurred under an arrangement must be allocated to the full range of services furnished to the hospital by the medical school physicians on the same basis as provided for under paragraph (j) of this section, and costs allocated to direct medical and surgical services furnished to hospital patients must be apportioned to beneficiaries as provided for under paragraph (g) of this section.

(C) If the medical school and the hospital are not related organizations under the provisions of § 413.17 of this chapter and the hospital makes payment to the medical school only for the costs of those services furnished to beneficiaries, costs of the medical school not to exceed 105 percent of the sum of physician direct salaries, applicable fringe benefits, employer's portion of FICA taxes, Federal and State unemployment taxes, and workmen's compensation paid by the medical school or an organization related to the medical school may be recognized as allowable costs of the medical school.

(D) These allowable medical school costs must be allocated to the full

range of services furnished by the physicians of the medical school or organization related as provided by paragraph (j) of this section.

(E) Costs allocated to direct medical and surgical services furnished to hospital patients must be apportioned to beneficiaries as provided by paragraph (g) of this section.

(2) *Reasonable costs of other than direct medical and surgical services.* These costs are determined in accordance with paragraph (c)(1) of this section except that—

(i) If the hospital makes payment to the medical school for other than direct medical and surgical services furnished to beneficiaries and supervision of interns and residents furnishing care to beneficiaries, these payments are subject to the required cost-finding and apportionment methods applicable to the cost of other hospital services (except for direct medical and surgical services furnished to beneficiaries); or

(ii) If the hospital makes payment to the medical school only for these services furnished to beneficiaries, the cost of these services is not subject to cost-finding and apportionment as otherwise provided by this subpart, and the reasonable cost paid by Medicare must be determined on the basis of the health insurance ratio(s) used in the apportionment of all other provider costs (excluding physician direct medical and surgical services furnished to beneficiaries) applied to the allowable medical school costs incurred by the medical school for the services furnished to all patients of the hospital.

(d) *''Salary equivalent'' payments for direct medical and surgical services furnished by physicians on the voluntary staff of the hospital.* (1) CMS makes payments under the Medicare program to a fund as defined in §415.164 for direct medical and surgical services furnished to beneficiaries on a regularly scheduled basis by physicians on the unpaid voluntary medical staff of the hospital (or medical school under arrangement with the hospital).

(i) These payments represent compensation for contributed medical staff time which, if not contributed, would have to be obtained through employed staff on a payable basis.

(ii) Payments for volunteer services are determined by applying to the regularly scheduled contributed time an hourly rate not to exceed the equivalent of the average direct salary (exclusive of fringe benefits) paid to all full-time, salaried physicians (other than interns and residents) on the hospital staff or, if the number of full-time salaried physicians is minimal in absolute terms or in relation to the number of physicians on the voluntary staff, to physicians at like institutions in the area.

(iii) This ''salary equivalent'' is a single hourly rate covering all physicians regardless of specialty and is applied to the actual regularly scheduled time contributed by the physicians in furnishing direct medical and surgical services to beneficiaries including supervision of interns and residents in that care.

(iv) A physician who receives any compensation from the hospital or a medical school related to the hospital by common ownership or control (within the meaning of §413.17 of this chapter) for direct medical and surgical services furnished to any patient in the hospital is not considered an unpaid voluntary physician for purposes of this paragraph.

(v) If, however, a physician receives compensation from the hospital or related medical school or organization only for services that are other than direct medical and surgical services, a salary equivalent payment for the physician's regularly scheduled direct medical and surgical services to beneficiaries in the hospital may be imputed. However, the sum of the imputed value for volunteer services and the physician's actual compensation from the hospital and the related medical school (or organization) may not exceed the amount that would have been imputed if all of the physician's hospital and medical school services (compensated and volunteer) had been volunteer services, or paid at the rate of $30,000 per year, whichever is less.

(2) The following examples illustrate how the allowable imputed value for volunteer services is determined. In each example, it has been assumed that the average salary equivalent hourly rate is equal to the hourly rate for the

individual physician's compensated services.

Example No: 1. Dr. Jones received $3,000 a year from Hospital X for services other than direct medical services to all patients, for example, utilization review and administrative services. Dr. Jones also voluntarily furnished direct medical services to beneficiaries. The imputed value of the volunteer services amounted to $10,000 for the cost reporting period. The full imputed value of Dr. Jones' volunteer direct medical services would be allowed since the total amount of the imputed value ($10,000) and the compensated services ($3,000) does not exceed $30,000.

Example No: 2. Dr. Smith received $25,000 from Hospital X for services as a department head in a teaching hospital. Dr. Smith also voluntarily furnished direct medical services to beneficiaries. The imputed value of the volunteer services amounted to $10,000. Only $5,000 of the imputed value of volunteer services would be allowed since the total amount of the imputed value ($10,000) and the compensated services ($25,000) exceeds the $30,000 maximum amount allowable for all of Dr. Smith's services.

COMPUTATION:

Maximum amount allowable for all services performed by Dr. Smith for purposes of this computation	$30,000
Less compensation received from Hospital X for other than direct medical services to individual patients	$25,000
Allowable amount of imputed value for the volunteer services furnished by Dr. Smith	$5,000

Example No. 3. Dr. Brown is not compensated by Hospital X for any services furnished in the hospital. Dr. Brown voluntarily furnished direct surgical services to beneficiaries for a period of 6 months, and the imputed value of these services amounted to $20,000. The allowable amount of the imputed value for volunteer services furnished by Dr. Brown would be limited to $15,000 ($30,000×6/12).

(3) The amount of the imputed value for volunteer services applicable to beneficiaries and payable to a fund is determined in accordance with the aggregate per diem method described in paragraph (g) of this section.

(4) Medicare payments to a fund must be used by the fund solely for improvement of care of hospital patients or for educational or charitable purposes (which may include but are not limited to medical and other scientific research).

(i) No personal financial gain, either direct or indirect, from benefits of the fund may inure to any of the hospital staff physicians, medical school faculty, or physicians for whom Medicare imputes costs for purposes of payment into the fund.

(ii) Expenses met from contributions made to the hospital from a fund are not included as a reimbursable cost when expended by the hospital, and depreciation expense is not allowed with respect to equipment or facilities donated to the hospital by a fund or purchased by the hospital from monies in a fund.

(e) *Requirements for payment*—(1) *Physicians on the hospital staff.* The requirements under which the costs of physician direct medical and surgical services (including supervision of interns and residents) to beneficiaries are the same as those applicable to the cost of all other covered provider services except that the costs of these services are separately determined as provided by this section and are not subject to cost-finding as described in § 413.24 of this chapter.

(2) *Physicians on the medical school faculty.* Payment is made to a hospital for the costs of services of physicians on the medical school faculty, provided that if the medical school is not related to the hospital (within the meaning of § 413.17 of this chapter, concerning cost to related organizations), the hospital does not make payment to the medical school for services furnished to all patients and the following requirements are met: If the hospital makes payment to the medical school for services furnished to all patients, these requirements do not apply. (See paragraph (c)(1)(ii) of this section.)

(i) There is a written agreement between the hospital and the medical school or organization, specifying the types and extent of services to be furnished by the medical school and specifying that the hospital must pay to the medical school an amount at least equal to the reasonable cost (as defined in paragraph (c) of this section) of furnishing the services to beneficiaries.

(ii) The costs are paid to the medical school by the hospital no later than

the date on which the cost report covering the period in which the services were furnished is due to CMS.

(iii) Payment for the services furnished under an arrangement would have been made to the hospital had the services been furnished directly by the hospital.

(3) *Physicians on the voluntary staff of the hospital (or medical school under arrangement with the hospital).* If the conditions for payment to a fund outlined in §415.164 are met, payments are made on a ''salary equivalent'' basis (as defined in paragraph (d) of this section) to a fund.

(f) *Requirements for payment for medical school faculty services other than physician direct medical and surgical services.* If the requirements for payment for physician direct medical and surgical services furnished to beneficiaries in a teaching hospital described in paragraph (e) of this section are met, payment is made to a hospital for the costs of medical school faculty services other than physician direct medical and surgical services furnished in a teaching hospital.

(g) *Aggregate per diem methods of apportionment*—(1) *For the costs of physician direct medical and surgical services.* The cost of physician direct medical and surgical services furnished in a teaching hospital to beneficiaries is determined on the basis of an average cost per diem as defined in paragraph (h)(1) of this section for physician direct medical and surgical services to all patients (see §§415.172 through 415.184) for each of the following categories of physicians:

(i) Physicians on the hospital staff.

(ii) Physicians on the medical school faculty.

(2) *For the imputed value of physician volunteer direct medical and surgical services.* The imputed value of physician direct medical and surgical services furnished to beneficiaries in a teaching hospital is determined on the basis of an average per diem, as defined in paragraph (h)(1) of this section, for physician direct medical and surgical services to all patients except that the average per diem is derived from the imputed value of the physician volunteer direct medical and surgical services furnished to all patients.

(h) *Definitions.* (1) *Average cost per diem for physician direct medical and surgical services (including supervision of interns and residents) furnished in a teaching hospital to patients in each category of physician services described in paragraph (g)(1) of this section* means the amount computed by dividing total reasonable costs of these services in each category by the sum of—

(i) Inpatient days (as defined in paragraph (h)(2) of this section); and

(ii) Outpatient visit days (as defined in paragraph (h)(3) of this section).

(2) *Inpatient days* are determined by counting the day of admission as 3.5 days and each day after a patient's day of admission, except the day of discharge, as 1 day.

(3) *Outpatient visit days* are determined by counting only one visit day for each calendar day that a patient visits an outpatient department or multiple outpatient departments.

(i) *Application.* (1) The following illustrates how apportionment based on the aggregate per diem method for costs of physician direct medical and surgical services furnished in a teaching hospital to patients is determined.

TEACHING HOSPITAL Y

Statistical and financial data:

Total inpatient days as defined in paragraph (h)(2) of this section and outpatient visit days as defined in paragraph (h)(3) of this section	75,000
Total inpatient Part A days	20,000
Total inpatient Part B days where Part A coverage is not available	1,000
Total outpatient Part B visit days	5,000
Total cost of direct medical and surgical services furnished to all patients by physicians on the hospital staff as determined in accordance with paragraph (i) of this section	$1,500,000
Total cost of direct medical and surgical services furnished to all patients by physicians on the medical school faculty as determined in accordance with paragraph (i) of this section	$1,650,000

Computation of cost applicable to program for physicians on the hospital staff:

Average cost per diem for direct medical and surgical services to patients by physicians on the hospital staff: $1,500,000 ÷ 75,000 = $20 per diem.

Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $20 per diem × 20,000	$400,000
Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $20 per diem × 1,000	$20,000
Cost of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $20 per diem × 5,000	$100,000

Computation of cost applicable to program for physicians on the medical school faculty:

Average cost per diem for direct medical and surgical services to patients by physicians on the medical school faculty: $1,650,000 ÷ 75,000 = $22 per diem.

Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $22 per diem × 20,000	$440,000
Cost of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $20 per diem × 1,000	$22,000
Cost of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $22 per diem × 5,000	$110,000

(2) The following illustrates how the imputed value of physician volunteer direct medical and surgical services furnished in a teaching hospital to beneficiaries is determined.

Example: The physicians on the medical staff of Teaching Hospital Y donated a total of 5,000 hours in furnishing direct medical and surgical services to patients of the hospital during a cost reporting period and did not receive any compensation from either the hospital or the medical school. Also, the imputed value for any physician volunteer services did not exceed the rate of $30,000 per year per physician.

STATISTICAL AND FINANCIAL DATA:

Total salaries paid to the full-time salaried physicians by the hospital (excluding interns and residents)	$800,000
Total physicians who were paid for an average of 40 hours per week or 2,080 (52 weeks×40 hours per week) hours per year	20
Average hourly rate equivalent: $800,000 ÷ 41,600 (2,080 × 20)	$19.23

Computation of total imputed value of physician volunteer services applicable to all patients:

(Total donated hours × average hourly rate equivalent): 5,000 × $19.23	$96,150
Total inpatient days (as defined in paragraph (h)(2) of this section) and outpatient visit days (as defined in paragraph (h)(3) of this section)	75,000
Total inpatient Part A days	20,000
Total inpatient Part B days if Part A coverage is not available	1,000
Total outpatient Part B visit days	5,000

Computation of imputed value of physician volunteer direct medical and surgical services furnished to Medicare beneficiaries:

Average per diem for physician direct medical and surgical services to all patients: $96,150 ÷ 75,000 = $1.28 per diem

Imputed value of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part A: $1.28 per diem × 20,000	$25,600
Imputed value of physician direct medical and surgical services furnished to inpatient beneficiaries covered under Part B: $1.28 per diem × 1,000	$1,280
Imputed value of physician direct medical and surgical services furnished to outpatient beneficiaries covered under Part B: $1.28 per diem × 5,000	$6,400
Total	$33,280

(j) *Allocation of compensation paid to physicians in a teaching hospital.* (1) In determining reasonable cost under this section, the compensation paid by a teaching hospital, or a medical school or related organization under arrangement with the hospital, to physicians in a teaching hospital must be allocated to the full range of services implicit in the physician compensation arrangements. (However, see paragraph (d) of this section for the computation of the ''salary equivalent'' payments for volunteer services furnished to patients.)

(2) This allocation must be made and must be capable of substantiation on the basis of the proportion of each physician's time spent in furnishing each type of service to the hospital or medical school.

§415.164 Payment to a fund.

(a) *General rules.* Payment for certain voluntary services by physicians in teaching hospitals (as these services are described in §415.160) is made on a salary equivalent basis (as described in §415.162(d)) subject to the conditions and limitations contained in parts 405 and 413 of this chapter and this part 415, to a single fund (as defined in paragraph (b) of this section) designated by the organized medical staff of the hospital (or, if the services are furnished in the hospital by the faculty of a medical school, to a fund as may be designated by the faculty), if the following conditions are met:

(1) The hospital (or medical school furnishing the services under arrangement with the hospital) incurs no actual cost in furnishing the services.

(2) The hospital has an agreement with CMS under part 489 of this chapter.

(3) The intermediary, or CMS as appropriate, has received written assurances that—

(i) The payment is used solely for the improvement of care of hospital patients or for educational or charitable purposes; and

(ii) Neither the individuals who are furnished the services nor any other persons are charged for the services (and if charged, provision is made for the return of any monies incorrectly collected).

(b) *Definition of a fund.* For purposes of paragraph (a) of this section, a *fund* is an organization that meets either of the following requirements:

(1) The organization has and retains exemption, as a governmental entity or under section 501(c)(3) of the Internal Revenue Code (nonprofit educational, charitable, and similar organizations), from Federal taxation.

(2) The organization is an organization of physicians who, under the terms of their employment by an entity that meets the requirements of paragraph (b)(1) of this section, are required to turn over to that entity all income that the physician organization derives from the physician services.

(c) *Status of a fund.* A fund approved for payment under paragraph (a) of this section has all the rights and responsibilities of a provider under Medicare except that it does not enter into an agreement with CMS under part 489 of this chapter.

§415.170 Conditions for payment on a fee schedule basis for physician services in a teaching setting.

Services meeting the conditions for payment in §415.102(a) furnished in teaching settings are payable under the physician fee schedule if—

(a) The services are personally furnished by a physician who is not a resident; or

(b) The services are furnished by a resident in the presence of a teaching physician except as provided in §415.172 (concerning physician fee schedule payment for services of teaching physicians), §415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), §415.176 (concerning renal dialysis services), and §415.184 (concerning psychiatric services), as applicable.

§415.172 Physician fee schedule payment for services of teaching physicians.

(a) *General rule.* If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought.

(1) In the case of surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure.

(i) In the case of surgery, the teaching physician's presence is not required during opening and closing of the surgical field.

(ii) In the case of procedures performed through an endoscope, the teaching physician must be present during the entire viewing.

(2) In the case of evaluation and management services, the teaching physician must be present during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management

services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(b) *Documentation.* Except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures may be demonstrated by the notes in the medical records made by a physician, resident, or nurse. In the case of evaluation and management procedures, the teaching physician must personally document his or her participation in the service in the medical records.

(c) *Payment level.* In the case of services such as evaluation and management for which there are several levels of service codes available for reporting purposes, the appropriate payment level must reflect the extent and complexity of the service when fully furnished by the teaching physician.

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

(a) In the case of certain evaluation and management codes of lower and mid-level complexity (as specified by CMS in program instructions), carriers may make physician fee schedule payment for a service furnished by a resident without the presence of a teaching physician. For the exception to apply, all of the following conditions must be met:

(1) The services must be furnished in a center that is located in an outpatient department of a hospital or another ambulatory care entity in which the time spent by residents in patient care activities is included in determining intermediary payments to a hospital under §§ 413.75 through 413.83.

(2) Any resident furnishing the service without the presence of a teaching physician must have completed more than 6 months of an approved residency program.

(3) The teaching physician must not direct the care of more than four residents at any given time and must direct the care from such proximity as to constitute immediate availability. The teaching physician must—

(i) Have no other responsibilities at the time;

(ii) Assume management responsibility for those beneficiaries seen by the residents;

(iii) Ensure that the services furnished are appropriate;

(iv) Review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies; and

(v) Document the extent of the teaching physician's participation in the review and direction of the services furnished to each beneficiary.

(4) The range of services furnished by residents in the center includes all of the following:

(i) Acute care for undifferentiated problems or chronic care for ongoing conditions.

(ii) Coordination of care furnished by other physicians and providers.

(iii) Comprehensive care not limited by organ system, or diagnosis.

(5) The patients seen must be an identifiable group of individuals who consider the center to be the continuing source of their health care and in which services are furnished by residents under the medical direction of teaching physicians.

(b) Nothing in paragraph (a) of this section may be construed as providing a basis for the coverage of services not determined to be covered under Medicare, such as routine physical checkups.

[60 FR 63178, Dec. 8, 1995, as amended at 61 FR 59554, Nov. 22, 1996; 70 FR 47490, Aug. 12, 2005]

§ 415.176 Renal dialysis services.

In the case of renal dialysis services, physicians who are not paid under the physician monthly capitation payment method (as described in § 414.314 of this chapter) must meet the requirements of §§ 415.170 and 415.172 (concerning physician fee schedule payment for services of teaching physicians).

§415.178 Anesthesia services.

(a) *General rule.* An unreduced physician fee schedule payment may be made if a physician is involved in a single anesthesia procedure involving an anesthesia resident. In the case of anesthesia services, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure. The teaching physician cannot receive an unreduced fee if he or she performs services involving other patients during the period the anesthesia resident is furnishing services in a single case. For additional rules for payment of anesthesia services involving residents, see §414.46(c)(1)(iii)).

(b) *Documentation.* Documentation must indicate the physician's presence or participation in the administration of the anesthesia.

[60 FR 63178, Dec. 8, 1995; 61 FR 42385, Aug. 15, 1996]

§415.180 Teaching setting requirements for the interpretation of diagnostic radiology and other diagnostic tests.

(a) *General rule.* Physician fee schedule payment is made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed or reviewed by a physician other than a resident.

(b) *Documentation.* Documentation must indicate that the physician personally performed the interpretation or reviewed the resident's interpretation with the resident.

§415.184 Psychiatric services.

To qualify for physician fee schedule payment for psychiatric services furnished under an approved GME program, the physician must meet the requirements of §§415.170 and 415.172, including documentation, except that the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device.

§415.190 Conditions of payment: Assistants at surgery in teaching hospitals.

(a) *Basis, purpose, and scope.* This section describes the conditions under which Medicare pays on a fee schedule basis for the services of an assistant at surgery in a teaching hospital. This section is based on section 1842(b)(7)(D)(I) of the Act and applies only to hospitals with an approved GME residency program. Except as specified in paragraph (c) of this section, fee schedule payment is not available for assistants at surgery in hospitals with—

(1) A training program relating to the medical specialty required for the surgical procedure; and

(2) A resident in a training program relating to the specialty required for the surgery available to serve as an assistant at surgery.

(b) *Definition. Assistant at surgery* means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

(c) *Conditions for payment for assistants at surgery.* Payment on a fee schedule basis is made for the services of an assistant at surgery in a teaching hospital only if the services meet one of the following conditions:

(1) Are required as a result of exceptional medical circumstances.

(2) Are complex medical procedures performed by a team of physicians, each performing a discrete, unique function integral to the performance of a complex medical procedure that requires the special skills of more than one physician.

(3) Constitute concurrent medical care relating to a medical condition that requires the presence of, and active care by, a physician of another specialty during surgery.

(4) Are medically required and are furnished by a physician who is primarily engaged in the field of surgery, and the primary surgeon does not use interns and residents in the surgical procedures that the surgeon performs (including preoperative and postoperative care).

(5) Are not related to a surgical procedure for which CMS determines that assistants are used less than 5 percent of the time.

Subpart E—Services of Residents

§ 415.200 Services of residents in approved GME programs.

(a) *General rules.* Services furnished in hospitals by residents in approved GME programs are specifically excluded from being paid as ''physician services'' defined in § 414.2 of this chapter and are payable as hospital services. This exclusion applies whether or not the resident is licensed to practice under the laws of the State in which he or she performs the service. The payment methodology for services of residents in hospitals and hospital-based providers is set forth in §§ 413.75 through 413.83 of this chapter.

(b) *Exception.* For low and mid-level evaluation and management services furnished under certain conditions in centers located in hospital outpatient departments and other ambulatory settings, see § 415.174.

(c) *Definitions.* See § 415.152 for definitions of terms used in this subpart E.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.202 Services of residents not in approved GME programs.

(a) *General rules.* For services of a physician employed by a hospital who is authorized to practice only in a hospital setting and for the services of a resident who is not in any approved GME program, payment is made to the hospital on a Part B reasonable cost basis regardless of whether the services are furnished to hospital inpatients or outpatients.

(b) *Payment.* For services described in paragraph (a) of this section, payment is made under Part B by reducing the reasonable costs of furnishing the services by the beneficiary deductible and paying 80 percent of the remaining amount. No payment is made for other costs of unapproved programs, such as administrative costs related to teaching activities of physicians.

§ 415.204 Services of residents in skilled nursing facilities and home health agencies.

(a) *Medicare Part A payment.* Payment is made under Medicare Part A for interns' and residents' services furnished in the following settings that meet the specified requirements:

(1) *Skilled nursing facility.* Payment to a participating skilled nursing facility may include the cost of services of an intern or resident who is in an approved GME program in a hospital with which the skilled nursing facility has a transfer agreement that provides, in part, for the transfer of patients and the interchange of medical records.

(2) *Home health agency.* A participating home health agency may receive payment for the cost of the services of an intern or resident who is under an approved GME program of a hospital with which the home health agency is affiliated or under common control if these services are furnished as part of the home health visits for a Medicare beneficiary. (Nevertheless, see §§ 413.75 through 413.83 of this chapter for the costs of approved GME programs in hospital-based providers.)

(b) *Medicare Part B payment.* Medical services of a resident of a hospital that are furnished by a skilled nursing facility or home health agency are paid under Medicare Part B if payment is not provided under Medicare Part A. Payment is made under Part B for a resident's services by reducing the reasonable costs of furnishing the services by the beneficiary deductible and paying 80 percent of the remaining amount.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.206 Services of residents in nonprovider settings.

Patient care activities of residents in approved GME programs that are furnished in nonprovider settings are payable in one of the following two ways:

(a) *Direct GME payments.* If the conditions in § 413.78 regarding patient care activities and training of residents are met, the time residents spend in nonprovider settings such as clinics, nursing facilities, and physician offices in connection with approved GME programs is included in determining the number of full-time equivalency residents in the calculation of a teaching hospital's resident count. The teaching physician rules on carrier payments in §§ 415.170 through 415.184 apply in these teaching settings.

(b) *Physician fee schedule.* (1) Services furnished by a resident in a nonprovider setting are covered as physician services and payable under the physician fee schedule if the following requirements are met:

(i) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry in the State in which the service is performed.

(ii) The time spent in patient care activities in the nonprovider setting is not included in a teaching hospital's full-time equivalency resident count for the purpose of direct GME payments.

(2) Payment may be made regardless of whether a resident is functioning within the scope of his or her GME program in the nonprovider setting.

(3) If fee schedule payment is made for the resident's services in a nonprovider setting, payment must not be made for the services of a teaching physician.

(4) The carrier must apply the physician fee schedule payment rules set forth in subpart A of part 414 of this chapter to payments for services furnished by a resident in a nonprovider setting.

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

§ 415.208 Services of moonlighting residents.

(a) *Definition.* For purposes of this section, the term *services of moonlighting residents* refers to services that licensed residents perform that are outside the scope of an approved GME program.

(b) *Services in GME program hospitals.* (1) The services of residents to inpatients of hospitals in which the residents have their approved GME program are not covered as physician services and are payable under §§ 413.75 through 413.83 regarding direct GME payments.

(2) Services of residents that are not related to their approved GME programs and are performed in an outpatient department or emergency department of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if all of the following criteria are met:

(i) The services are identifiable physician services and meet the conditions for payment of physician services to beneficiaries in providers in § 415.102(a).

(ii) The resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed.

(iii) The services performed can be separately identified from those services that are required as part of the approved GME program.

(3) If the criteria specified in paragraph (b)(2) of this section are met, the services of the moonlighting resident are considered to have been furnished by the individual in his or her capacity as a physician, rather than in the capacity of a resident. The carrier must review the contracts and agreements for these services to ensure compliance with the criteria specified in paragraph (b)(2) of this section.

(4) No payment is made for services of a ''teaching physician'' associated with moonlighting services, and the time spent furnishing these services is not included in the teaching hospital's full-time equivalency count for the indirect GME payment (§ 412.105 of this chapter) and for the direct GME payment (§§ 413.75 through 413.83 of this chapter).

(c) *Other settings.* Moonlighting services of a licensed resident in an approved GME program furnished outside the scope of that program in a hospital or other setting that does not participate in the approved GME program are payable under the physician fee schedule as set forth in § 415.206(b)(1).

[60 FR 63178, Dec. 8, 1995, as amended at 70 FR 47490, Aug. 12, 2005]

PART 416—AMBULATORY SURGICAL SERVICES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 47 FR 34094, Aug. 5, 1982, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 416.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1832(a)(2)(F)(i) of the Act provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary under section 1833(i)(1) of the Act.

(2) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ambulatory surgical center, or a hospital outpatient department.

(3) Section 1833(i) (2)(A) and (3) specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed, respectively, in an ASC, or in a hospital outpatient department.

(b) *Scope.* This part sets forth—

(1) The conditions that an ASC must meet in order to participate in the Medicare program;

(2) The scope of covered services; and

(3) The conditions for Medicare payment for facility services.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§ 416.2 Definitions.

As used in this part:

Ambulatory surgical center or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

ASC services means facility services that are furnished in an ASC.

Covered surgical procedures means those surgical and other medical procedures that meet the criteria specified in § 416.65 and are published by CMS in the FEDERAL REGISTER.

Facility services means services that are furnished in connection with covered surgical procedures performed in an ASC, or in a hospital on an outpatient basis.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

Subpart B—General Conditions and Requirements

§ 416.25 Basic requirements.

Participation as an ASC is limited to facilities that—

(a) Meet the definition in § 416.2; and

(b) Have in effect an agreement obtained in accordance with this subpart.

[56 FR 8843, Mar. 1, 1991]

§ 416.26 Qualifying for an agreement.

(a) *Deemed compliance*. CMS may deem an ASC to be in compliance with any or all of the conditions set forth in subpart C of this part if—

(1) The ASC is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;

(2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

(3) The ASC authorizes the release to CMS, of the findings of the accreditation survey.

(b) *Survey of ASCs*. (1) Unless CMS deems the ASC to be in compliance with the conditions set forth in subpart C of this part, the State survey agency must survey the facility to ascertain compliance with those conditions, and report its findings to CMS.

(2) CMS surveys deemed ASCs on a sample basis as part of CMS's validation process.

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services*. If CMS determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this part, it sends to the ASC—

(1) Written notice of the determination; and

(2) Two copies of the ASC agreement.

(d) *Filing of agreement by the ASC*. If the ASC wishes to participate in the program, it must—

(1) Have both copies of the ASC agreement signed by its authorized representative; and

(2) File them with CMS.

(e) *Acceptance by CMS*. If CMS accepts the agreement filed by the ASC, returns to the ASC one copy of the agreement, with a notice of acceptance specifying the effective date.

(f) *Appeal rights*. If CMS refuses to enter into an agreement or if CMS terminates an agreement, the ASC is entitled to a hearing in accordance with part 498 of this chapter.

[56 FR 8843, Mar. 1, 1991]

§ 416.30 Terms of agreement with CMS.

As part of the agreement under § 416.26 the ASC must agree to the following:

(a) *Compliance with coverage conditions*. The ASC agrees to meet the conditions for coverage specified in subpart C of this part and to report promptly to CMS any failure to do so.

(b) *Limitation on charges to beneficiaries*.[1] The ASC agrees to charge the beneficiary or any other person only the applicable deductible and coinsurance amounts for facility services for which the beneficiary—

(1) Is entitled to have payment made on his or her behalf under this part; or

(2) Would have been so entitled if the ASC had filed a request for payment in accordance with § 410.165 of this chapter.

(c) *Refunds to beneficiaries*. (1) The ASC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(2) As used in this section, *money incorrectly collected* means sums collected in excess of those specified in paragraph (b) of this section. It includes amounts collected for a period of time when the beneficiary was believed not to be entitled to Medicare benefits if—

(i) The beneficiary is later determined to have been entitled to Medicare benefits; and

(ii) The beneficiary's entitlement period falls within the time the ASC's agreement with CMS is in effect.

[1] For facility services furnished before July 1987, the ASC had to agree to make no charge to the beneficiary, since those services were not subject to the part B deductible and coinsurance provisions.

(d) *Furnishing information.* The ASC agrees to furnish to CMS, if requested, information necessary to establish payment rates specified in §§ 416.120–416.130 in the form and manner that CMS requires.

(e) *Acceptance of assignment.* The ASC agrees to accept assignment for all facility services furnished in connection with covered surgical procedures. For purposes of this section, assignment means an assignment under § 424.55 of this chapter of the right to receive payment under Medicare Part B and payment under § 424.64 of this chapter (when an individual dies before assigning the claim).

(f) *ASCs operated by a hopsital.* In an ASC operated by a hospital—

(1) The agreement is made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC; and

(2) The ASC participates and is paid only as an ASC, without the option of converting to or being paid as a hospital outpatient department, unless CMS determines there is good cause to do otherwise.

(3) Costs for the ASC are treated as a non-reimbursable cost center on the hopsital's cost report.

(g) *Additional provisions.* The agreement may contain any additional provisions that CMS finds necessary or desirable for the efficient and effective administration of the Medicare program.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 41351, Nov. 14, 1986; 56 FR 8844, Mar. 1, 1991]

§ 416.35 Termination of agreement.

(a) *Termination by the ASC*—(1) *Notice to CMS.* An ASC that wishes to terminate its agreement must send CMS written notice of its intent.

(2) *Date of termination.* The notice may state the intended date of termination which must be the first day of a calendar month.

(i) If the notice does not specify a date, or the date is not acceptable to CMS, CMS may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) CMS may accept a termination date that is less than 6 months after the date on the ASC's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Voluntary termination.* If an ASC ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) *Termination by CMS*—(1) *Cause for termination.* CMS may terminate an agreement if it determines that the ASC—

(i) No longer meets the conditions for coverage as specified under § 416.26; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, and other applicable regulations of subchapter B of this chapter, or any applicable provisions of title XVIII of the Act.

(2) *Notice of termination.* CMS sends notice of termination to the ASC at least 15 days before the effective date stated in the notice.

(3) *Appeal by the ASC.* An ASC may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment is not available for ASC services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination is given to the public, through publication in local newspapers by—

(1) The ASC, after CMS has approved or set a termination date; or

(2) CMS, when it has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by CMS.* When an agreement with an ASC is terminated by CMS, the ASC may not file another agreement to participate in the Medicare program unless CMS—

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[47 FR 34094, Aug. 5, 1982, as amended at 52 FR 22454, June 12, 1987; 56 FR 8844, Mar. 1, 1991; 61 FR 40347, Aug. 2, 1996]

Subpart C—Specific Conditions for Coverage

§416.40 Condition for coverage—Compliance with State licensure law.

The ASC must comply with State licensure requirements.

§416.41 Condition for coverage—Governing body and management.

The ASC must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. *Standard: Hospitalization.* The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter. The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 22041, June 17, 1986]

§416.42 Condition for coverage—Surgical services.

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(a) *Standard: Anesthetic risk and evaluation.* A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

(b) *Standard: Administration of anesthesia.* Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

(c) *Standard: Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

(d) *Standard: State exemption.* (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[57 FR 33899, July 31, 1992, as amended at 66 FR 56768, Nov. 13, 2001.]

§416.43 Condition for coverage—Evaluation of quality.

The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of

care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

§ 416.44 Condition for coverage—Environment.

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(a) *Standard: Physical environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

(2) The ASC must have a separate recovery room and waiting area.

(3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

(b) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with the following provisions:

(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);

(B) The maximum individual dispenser fluid capacity shall be:

(*1*) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.

(*2*) 0.5 gallons (2.0 liters) for dispensers in suites of rooms;

(C) The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other;

(D) Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;

(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single

smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code;*

(F) The dispensers shall not be installed over or directly adjacent to an ignition source; and

(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

(c) *Standard: Emergency equipment.* Emergency equipment available to the operating rooms must include at least the following:

(1) Emergency call system.

(2) Oxygen.

(3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator.

(4) Cardiac defibrillator.

(5) Cardiac monitoring equipment.

(6) Tracheostomy set.

(7) Laryngoscopes and endotracheal tubes.

(8) Suction equipment.

(9) Emergency medical equipment and supplies specified by the medical staff.

(d) *Standard: Emergency personnel.* Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988; 54 FR 4026, Jan. 27, 1989; 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 70 FR 15237, Mar. 25, 2005]

§ 416.45 Condition for coverage—Medical staff.

The medical staff of the ASC must be accountable to the governing body.

(a) *Standard: Membership and clinical privileges.* Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

(b) *Standard: Reappraisals.* Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

(c) *Standard: Other practitioners.* If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

§ 416.46 Condition for coverage—Nursing services.

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

(a) *Standard: Organization and staffing.* Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

(b) [Reserved]

§ 416.47 Condition for coverage—Medical records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

(a) *Standard: Organization.* The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(b) *Standard: Form and content of record.* The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

(1) Patient identification.

(2) Significant medical history and results of physical examination.

(3) Pre-operative diagnostic studies (entered before surgery), if performed.

(4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.

(5) Any allergies and abnormal drug reactions.

(6) Entries related to anesthesia administration.

(7) Documentation of properly executed informed patient consent.

(8) Discharge diagnosis.

§ 416.48 Condition for coverage—Pharmaceutical services.

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

(a) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood and blood products must be administered by only physicians or registered nurses.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

(b) [Reserved]

§ 416.49 Condition for coverage—Laboratory and radiologic services.

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493 of this chapter. The ASC must have procedures for obtaining radiologic services from a Medicare approved facility to meet the needs of patients.

[57 FR 7135, Feb. 28, 1992]

Subpart D—Scope of Benefits

§ 416.60 General rules.

(a) The services payable under this part are facility services furnished to Medicare beneficiaries, by a participating facility, in connection with covered surgical procedures specified in § 416.65.

(b) The surgical procedures, including all preoperative and post-operative services that are performed by a physician, are covered as physician services under part 410 of this chapter.

[56 FR 8844, Mar. 1, 1991]

§ 416.61 Scope of facility services.

(a) *Included services.* Facility services include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facilities where the surgical procedures are performed;

(3) Drugs, biologicals, surgical dressings, supplies, splints, casts, and appliances and equipment directly related to the provision of surgical procedures;

(4) Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure;

(5) Administrative, recordkeeping and housekeeping items and services; and

(6) Materials for anesthesia.

(7) Intra-ocular lenses (IOLs).

(8) Supervision of the services of an anesthetist by the operating surgeon.

(b) *Excluded services.* Facility services do not include items and services for which payment may be made under other provisions of part 405 of this chapter, such as physicians' services, laboratory, X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure), prosthetic devices (except IOLs), ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home. In addition, they do not include anesthetist services furnished on or after January 1, 1989.

[56 FR 8844, Mar. 1, 1991, as amended at 57 FR 33899, July 31, 1992]

§ 416.65 Covered surgical procedures.

Covered surgical procedures are those procedures that meet the standards described in paragraphs (a) and (b) of this section and are included in the list published in accordance with paragraph (c) of this section.

(a) *General standards.* Covered surgical procedures are those surgical and other medical procedures that—

(1) Are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC;

(2) Are not of a type that are commonly performed, or that may be safely performed, in physicians' offices;

(3) Are limited to those requiring a dedicated operating room (or suite), and generally requiring a post-operative recovery room or short-term (not overnight) convalescent room; and

(4) Are not otherwise excluded under §405.310 of this chapter.

(b) *Specific standards.* (1) Covered surgical procedures are limited to those that do not generally exceed—

(i) A total of 90 minutes operating time; and

(ii) A total of 4 hours recovery or convalescent time.

(2) If the covered surgical procedures require anesthesia, the anesthesia must be—

(i) Local or regional anesthesia; or

(ii) General anesthesia of 90 minutes or less duration.

(3) Covered surgical procedures may not be of a type that—

(i) Generally result in extensive blood loss;

(ii) Require major or prolonged invasion of body cavities;

(iii) Directly involve major blood vessels; or

(iv) Are generally emergency or life-threatening in nature.

(c) *Publication of covered procedures.* CMS will publish in the FEDERAL REGISTER a list of covered surgical procedures and revisions as appropriate.

§416.75 Performance of listed surgical procedures on an inpatient hospital basis.

The inclusion of any procedure as a covered surgical procedure under §416.65 does not preclude its coverage in an inpatient hospital setting under Medicare.

Subpart E—Payment for Facility Services

§416.120 Basis for payment.

The basis for payment depends on where the services are furnished.

(a) *Hospital outpatient department.* Payment is in accordance with part 413 of this chapter.

(b) [Reserved]

(c) *ASC*—(1) *General rule.* Payment is based on a prospectively determined rate. This rate covers the cost of services such as supplies, nursing services, equipment, etc., as specified in §416.61. The rate does not cover physician services or other medical services covered under part 410 of this chapter (for example, X-ray services or laboratory services) which are not directly related to the performance of the surgical procedures. Those services may be billed separately and paid on a reasonable charge basis.

(2) *Single and multiple surgical procedures.* (i) If one covered surgical procedure is furnished to a beneficiary in an operative session, payment is based on the prospectively determined rate for that procedure.

(ii) If more than one surgical procedure is furnished in a single operative session, payment is based on—

(A) The full rate for the procedure with the highest prospectively determined rate; and

(B) One half of the prospectively determined rate for each of the other procedures.

(3) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in §410.152 (a) and (i) of this chapter.

[56 FR 8844, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§416.125 ASC facility services payment rate.

(a) The payment rate is based on a prospectively determined standard overhead amount per procedure derived from an estimate of the costs incurred by ambulatory surgical centers generally in providing services furnished in connection with the performance of that procedure.

(b) The payment must be substantially less than would have been paid under the program if the procedure had been performed on an inpatient basis in a hospital.

[56 FR 8844, Mar. 1, 1991]

§416.130 Publication of revised payment methodologies.

Whenever CMS proposes to revise the payment rate for ASCs, CMS publishes a notice in the FEDERAL REGISTER describing the revision. The notice also explains the basis on which the rates

were established. After reviewing public comments, CMS publishes a notice establishing the rates authorized by this section. In setting these rates, CMS may adopt reasonable classifications of facilities and may establish different rates for different types of surgical procedures.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8844, Mar. 1, 1991]

§ 416.140 Surveys.

(a) *Timing, purpose, and procedures.* (1) No more often than once a year, CMS conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) CMS notifies the selected ASCs by mail of their selection and of the form and content of the report the ASCs are required to submit within 60 days of the notice.

(3) If the facility does not submit an adequate report in response to CMS's survey request, CMS may terminate the agreement to participate in the Medicare program as an ASC.

(4) CMS may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) *Requirements for ASCs.* ASCs must—

(1) Maintain adequate financial records, in the form and containing the data required by CMS, to allow determination of the payment rates for covered surgical procedures furnished to Medicare beneficiaries under this subpart.

(2) Within 60 days of a request from CMS submit, in the form and detail as may be required by CMS, a report of—

(i) Their operations, including the allowable costs actually incurred for the period and the actual number and kinds of surgical procedures furnished during the period; and

(ii) Their customary charges for each surgical procedure furnished for the period.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8845, Mar. 1, 1991]

§ 416.150 Beneficiary appeals.

A beneficiary (or ASC as his or her assignee) may request a hearing by a carrier (subject to the limitations and conditions set forth in part 405, subpart H of this chapter) if the beneficiary or the ASC—

(a) Is dissatisfied with a carrier's denial of a request for payment made on his or her behalf by an ASC;

(b) Is dissatisfied with the amount of payment; or

(c) Believes the request for payment is not being acted upon with reasonable promptness.

Subpart F—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

SOURCE: 64 FR 32205, June 16, 1999, unless otherwise noted.

§ 416.180 Definitions.

As used in this subpart, the following definitions apply:

Class of new technology intraocular lenses (IOLs) means all of the IOLs, collectively, that CMS determines meet the definition of ''new technology IOL'' under the provisions of this subpart.

Interested party means any individual, partnership, corporation, association, society, scientific or academic establishment, professional or trade organization, or any other legal entity.

New technology IOL means an IOL that CMS determines has been approved by the FDA for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

New technology subset means a group of IOLs that CMS determines meet the criterion for being treated as new technology IOLs and that share a common feature or features that distinguish them from other IOLs. For example, all new technology IOLs that are made of

a particular bioengineered material could comprise one subset, while all that rely on a particular optical innovation could comprise another.

§416.185 Payment review process.

(a) CMS publishes a FEDERAL REGISTER notice announcing the deadline and requirements for submitting a request for CMS to review payment for an IOL.

(b) CMS receives a request to review the appropriateness of the payment amount for an IOL.

(c) CMS compiles a list of the requests it receives and identifies the IOL manufacturer's name, the model number of the IOL to be reviewed, the interested party or parties that submit requests, and a summary of the interested party's grounds for requesting review of the appropriateness of the IOL payment amount.

(d) CMS publishes the list of requests in a FEDERAL REGISTER notice with comment period, giving the public 30 days to comment on the IOLs for which review was requested.

(e) CMS reviews the information submitted with the request to review, any timely public comments that are submitted regarding the list of IOLs published in the FEDERAL REGISTER, and any other timely information that CMS deems relevant to decide whether to provide a payment adjustment as specified in §416.200. CMS makes a determination of whether the IOL meets the definition of a new technology IOL in §416.180.

(f) If CMS determines that a lens is a new technology IOL, CMS establishes a payment adjustment as follows:

(1) Before July 16, 2002—$50.

(2) After July 16, 2002—$50 or the amount announced through proposed and final rulemaking in connection with ambulatory surgical center services.

(g) CMS designates a predominant characteristic of a new technology IOL that both sets it apart from other IOLs and links it with other similar IOLs with the same characteristic to establish a specific subset of new technology within the ''class of new technology IOLs.''

(h) Within 90 days of the end of the comment period following the FEDERAL REGISTER notice identified in paragraph (d) of this section, CMS publishes in the FEDERAL REGISTER its determinations with regard to IOLs that it has determined are ''new technology'' lenses that qualify for a payment adjustment.

(i) Payment adjustments are effective beginning 30 days after the publication of CMS's determinations in the FEDERAL REGISTER.

§416.190 Who may request a review.

Any party who is able to furnish the information required in §416.195 may request that CMS review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the definition of a new technology IOL in §416.180.

§416.195 A request to review.

(a) *Content of a request*. The request must include all of the following information:

(1) The name of the manufacturer, the model number, and the trade name of the IOL.

(2) A copy of the FDA's summary of the IOL's safety and effectiveness.

(3) A copy of the labeling claims of specific clinical advantages approved by the FDA for the IOL.

(4) A copy of the IOL's original FDA approval notification.

(5) Reports of modifications made after the original FDA approval.

(6) Other information that CMS finds necessary for identification of the IOL.

(b) *Confidential information*. To the extent that information received from an IOL manufacturer can reasonably be characterized as a trade secret or as privileged or confidential commercial or financial information, CMS maintains the confidentiality of the information and protects it from disclosure not otherwise authorized or required by Federal law as allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905).

§ 416.200 Application of the payment adjustment.

(a) CMS recognizes the IOL(s) that define a new technology subset for purposes of this subpart as belonging to the class of new technology IOLs for a period of 5 years effective from the date that CMS recognizes the first new technology IOL for a payment adjustment.

(b) Any IOL that CMS subsequently recognizes as belonging to a new technology subset receives the new technology payment adjustment for the remainder of the 5-year period established with CMS's recognition of the first IOL in the subset.

(c) Beginning 5 years after the effective date of CMS's initial recognition of a new technology subset, payment adjustments cease for all IOLs that CMS designates as belonging to that subset and payment reverts to the standard payment rate set under section 1833(i)(2)(A)(iii) of the Act for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by CMS as belonging to the class of new technology IOLs must submit claims using specific billing codes to receive the new technology IOL payment adjustment.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs.

1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart A—General Provisions

§417.1 Definitions.

As used in this part, unless the context indicates otherwise—

Basic health services means health services described in §417.101(a).

Community rating system means a system of fixing rates of payments for health services that meets the requirements of §417.104(a)(3).

Comprehensive health services means as a minimum the following services which may be limited as to time and cost:

(1) Physician services (§417.101(a)(1));

(2) Outpatient services and inpatient hospital services (§417.101(a)(2));

(3) Medically necessary emergency health services (§417.101(a)(3)); and

(4) Diagnostic laboratory and diagnostic and therapeutic radiologic services (§417.101(a)(6)).

Direct service contract means a contract for the provision of basic or supplemental health services or both between an HMO and (1) a health professional other than a member of the staff of the HMO, or (2) an entity other than a medical group or an IPA.

Enrollee means an individual for whom an HMO, CMP, or HCPP assumes the responsibility, under a contract or agreement, for the furnishing of health care services on a prepaid basis.

Full-time student means a student who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

Furnished, when used in connection with prepaid health care services, means services that are maid available to an enrollee either dierctly by, or under arrangements made by, the HMO, CMP, or HCPP.

Health maintenance organization (HMO) means a legal entity that provides or arranges for the provision of basic and supplemental health services to its enrollees in the manner prescribed by, is organized and operated in the manner prescribed by, and otherwise meets the requirements of, section 1301 of the PHS Act and the regulations in subparts B and C of this part.

Health professionals means physicians (doctors of medicine and doctors of osteopathy), dentists, nurses, podiatrists, optometrists, physicians' assistants, clinical psychologists, social workers, pharmacists, nutritionists, occupational therapists, physical therapists, and other professionals engaged in the delivery of health services who are licensed, practice under an institutional license, are certified, or practice under authority of the HMO, a medical group, individual practice association, or other authority consistent with State law.

Individual practice association (IPA) means a partnership, association, corporation, or other legal entity that delivers or arranges for the delivery of health services and which has entered into written services arrangement or arrangements with health professionals, a majority of whom are licensed to practice medicine or osteopathy. The written services arrangement must provide:

(1) That these health professionals will provide their professional services in accordance with a compensation arrangement established by the entity; and

(2) To the extent feasible, for the sharing by these health professionals of health (including medical) and other records, equipment, and professional, technical, and administrative staff.

Medical group means a partnership, association, corporation, or other group:

(1) That is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services for which the group is responsible;

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which:

(i) After the end of the 48 month period beginning after the month in

which the HMO for which the group provides health services becomes a qualified HMO, as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to enrollees of an HMO;

(ii) Pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services;

(iii) Share health (including medical) records and substantial portions of major equipment and of professional, technical, and administrative staff;

(iv) Establish an arrangement whereby an enrollee's enrollment status is not known to the health professional who provides health services to the enrollee.

Medical group members means (1) a health professional engaged as a partner, associate, or shareholder in the medical group, or (2) any other health professional employed by the group who may be designated as a medical group member by the medical group.

Medically underserved population means the population of an urban or rural area as described in Sec. 417.912(d).

Nonmetropolitan area means an area no part of which is within a standard metropolitan statistical area as designated by the Office of Management and Budget and which does not contain a city whose population exceeds 50,000 individuals.

Party in interest means: (1) Any director, officer, partner, or employee responsible for management or administration of an HMO, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the HMO, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the assets of the HMO, and, in the case of an HMO organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law;

(2) Any entity in which a person described in paragraph (1):

(i) Is an officer or director;

(ii) Is a partner (if the entity is organized as a partnership);

(iii) Has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(iv) Has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(3) Any spouse, child, or parent of an individual described in paragraph (1).

Policymaking body of an HMO means a board of directors, governing body, or other body of individuals that has the authority to establish policy for the HMO.

Qualified HMO means an HMO found by CMS to be qualified within the meaning of section 1310 of the PHS Act and subpart D of this part.

Rural area means any area not listed as a place having a population of 2,500 or more in Document #PC(1)A, ''Number of Inhabitants,'' Table VI, ''Population of Places,'' and not listed as an urbanized area in Table XI, ''Population of Urbanized Areas'' of the same document (1970 Census or most recent update of this document, Bureau of Census, U.S. Department of Commerce).

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service area means a geographic area, defined through zip codes, census tracts, or other geographic measurements, that is the area, as determined by CMS, within which the HMO furnishes basic and supplemental health services and makes them available and accessible to all its enrollees in accordance with § 417.106(b).

Significant business transaction means any business transaction or series of transactions during any one fiscal year of the HMO, the total value of which exceeds the lesser of $25,000 or 5 percent of the total operating expenses of the HMO.

Staff of the HMO means health professionals who are employees of the HMO and who—

(1) Provide services to HMO enrollees at an HMO facility subject to the staff policies and operational procedures of the HMO;

(2) Engage in the coordinated practice of their profession and provide to enrollees of the HMO the health services that the HMO has contracted to provide;

(3) Share medical and other records, equipment, and professional, technical, and administrative staff of the HMO; and

(4) Provide their professional services in accordance with a compensation arrangement, other than fee-for-service, established by the HMO. This arrangement may include, but is not limited to, fee-for-time, retainer or salary.

Subscriber means an enrollee who has entered into a contractual relationship with the HMO or who is responsible for making payments for basic health services (and contracted for supplemental health services) to the HMO or on whose behalf these payments are made.

Supplemental health services means the health services described in §417.102(a).

Unusual or infrequently used health services means:

(1) Those health services that are projected to involve fewer than 1 percent of the encounters per year for the entire HMO enrollment, or,

(2) Those health services the provision of which, given the enrollment projection of the HMO and generally accepted staffing patterns, is projected will require less than 0.25 full time equivalent health professionals.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19338, May 5, 1982; 52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987. Redesignated and amended at 56 FR 51985, Oct. 17, 1991; 58 FR 38067, July 15, 1993; 60 FR 34887, July 5, 1995; 60 FR 45674, Sept. 1, 1995]

§417.2 Basis and scope.

(a) Subparts B through F of this part pertain to the Federal qualification of HMOs under title XIII of the Public Health Service (PHS) Act.

(b) Subparts G through R of this part set forth the rules for Medicare contracts with, and payment to, HMOs and competitive medical plans (CMPs) under section 1876 of the Act.

(c) Subpart U of this part pertains to Medicare payment to health care prepayment plans under section 1833(a)(1)(A) of the Act.

(d) Subpart V of this part applies to the administration of outstanding loans and loan guarantees previously granted under title XIII of the PHS Act.

[56 FR 51985, Oct. 17, 1991, as amended at 60 FR 45675, Sept. 1, 1995]

Subpart B—Qualified Health Maintenance Organizations: Services

§417.101 Health benefits plan: Basic health services.

(a) An HMO must provide or arrange for the provision of basic health services to its enrollees as needed and without limitations as to time and cost other than those prescribed in the PHS Act and these regulations, as follows:

(1) Physician services (including consultant and referral services by a physician), which must be provided by a licensed physician, or if a service of a physician may also be provided under applicable State law by other health professionals, an HMO may provide the service through these other health professionals;

(2)(i) Outpatient services, which must include diagnostic services, treatment services and x-ray services, for patients who are ambulatory and may be provided in a non-hospital based health care facility or at a hospital;

(ii) Inpatient hospital services, which must include but not be limited to, room and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, use of intensive care unit and services, x-ray services, laboratory, and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma;

(iii) Outpatient services and inpatient hospital services must include short-term rehabilitation services and physical therapy, the provision of

which the HMO determines can be expected to result in the significant improvement of a member's condition within a period of two months;

(3) Instructions to its enrollees on procedures to be followed to secure medically necessary emergency health services both in the service area and out of the service area;

(4) Twenty outpatient visits per enrollee per year, as may be necessary and appropriate for short-term evaluative or crisis intervention mental health services, or both;

(5) Diagnosis, medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs:

(i) Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs must include detoxification for alcoholism or drug abuse on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to the other required basic health services for the treatment of other medical conditions;

(ii) Referral services may be either for medical or for nonmedical ancillary services. Medical services must be a part of basic health services; nonmedical ancillary services (such as vocational rehabilitation and employment counseling) and prolonged rehabilitation services in a specialized inpatient or residential facility need not be a part of basic health services;

(6) Diagnostic laboratory and diagnostic and therapeutic radiologic services in support of basic health services;

(7) Home health services provided at an enrollee's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the HMO; and

(8) Preventive health services, which must be made available to members and must include at least the following:

(i) A broad range of voluntary family planning services;

(ii) Services for infertility;

(iii) Well-child care from birth;

(iv) Periodic health evaluations for adults;

(v) Eye and ear examinations for children through age 17, to determine the need for vision and hearing correction; and

(vi) Pediatric and adult immunizations, in accord with accepted medical practice.

(b) In addition, an HMO may include a health service described in § 417.102 as a supplemental health service in the basic health services that it provides or arranges for its enrollees for a basic health services payment.

(c) To the extent that a natural disaster, war, riot, civil insurrection, epidemic or any other emergency or similar event not within the control of an HMO results in the facilities, personnel, or financial resources of an HMO being unavailable to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of §§ 417.101 through 417.106 and §§ 417.168 and 417.169, the HMO is required only to make a good-faith effort to provide or arrange for the provision of the service, taking into account the impact of the event. For purposes of this paragraph, an event is not within the control of an HMO if the HMO cannot exercise influence or dominion over its occurrence.

(d) The following are not required to be provided as basic health services:

(1) Corrective appliances and artificial aids;

(2) Mental health services, except as required under section 1302(1)(D) of the PHS Act and paragraph (a)(4) of this section;

(3) Cosmetic surgery, unless medically necessary;

(4) Prescribed drugs and medicines incidental to outpatient care;

(5) Ambulance services, unless medically necessary;

(6) Care for military service connected disabilities for which the enrollee is legally entitled to services and for which facilities are reasonably available to this enrollee;

(7) Care for conditions that State or local law requires be treated in a public facility;

(8) Dental services;

(9) Vision and hearing care except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the PHS Act and paragraphs (a)(1) and (a)(8) of this section;

(10) Custodial or domiciliary care;

(11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;

(12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;

(13) Whole blood and blood plasma;

(14) Long-term physical therapy and rehabilitation;

(15) Durable medical equipment for home use (such as wheel chairs, surgical beds, respirators, dialysis machines); and

(16) Health services that are unusual and infrequently provided and not necessary for the protection of individual health, as approved by CMS upon application by the HMO.

(e) An HMO may not offer to provide or arrange for the provision of basic health services on a prepayment basis that do not include all the basic health services set forth in paragraph (a) of this section or that are limited as to time and cost except in a manner prescribed by this subpart.

[45 FR 72528, Oct. 31, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38077, July 15, 1993]

§417.102 Health benefits plan: Supplemental health services.

(a) An HMO may provide to its enrollees any health service that is not included as a basic health service under §417.101(a). These health services may be limited as to time and cost.

(b) An HMO must determine the level and scope of supplemental health services included with basic health services provided to its enrollees for a basic health services payment or those services offered to its enrollees as supplemental health services.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§417.103 Providers of basic and supplemental health services.

(a)(1) The HMO must provide that the services of health professionals that are provided as basic health services will, except as provided in paragraph (c) of this section, be provided or arranged for through (i) health professionals who are staff of the HMO, (ii) a medical group or groups, (iii) an IPA or IPAs, (iv) physicians or other health professionals under direct service contracts with the HMO for the provision of these services, or (v) any combination of staff, medical group or groups, IPA or IPAs, or physicians or other health professionals under direct service contracts with the HMO.

(2) A staff or medical group model HMO may have as providers of basic health services physicians who have also entered into written services arrangements with an IPA or IPAs, but only if either (i) these physicians number less than 50 percent of the physicians who have entered into arrangements with the IPA or IPAs, or (ii) if the sharing is 50 percent or greater, CMS approves the sharing as being consistent with the purposes of section 1310(b) of the PHS Act.

(3) After the 4 year period beginning with the month following the month in that an HMO becomes a qualified HMO, an entity that meets the requirements of the definition of medical group in §417.100, except for subdivision (3)(i) of that definition, may be considered a medical group if CMS determines that the principal professional activity (over 50 percent individually) of the entity's members is the coordinated practice of their profession, and if the HMO has demonstrated to the satisfaction of CMS that the entity is committed to the delivery of medical services on a prepaid group practice basis by either:

(i) Presenting a reasonable time-phased plan for the entity to achieve compliance with the ''substantial responsibility'' requirement of subdivision (3)(i) of the definition of ''medical group'' in §417.100. The HMO must update the plan annually and must demonstrate to the satisfaction of CMS that the entity is making continuous efforts and progress towards compliance with the requirements of the definition of ''medical group,'' or

(ii) Demonstrating that compliance by the entity with the ''substantial responsibility'' requirement is unreasonable or impractical because (A) the HMO serves a non-metropolitan or rural area as defined in §417.100, or (B) the entity is a multi-speciality group

that provides medical consultation upon referral on a regional or national basis, or (C) the majority of the residents of the HMO's service area are not eligible for employer-employee health benefits plans and the HMO has an insufficient number of enrollees to require utilization of at least 35 percent of the entity's services.

(b) HMOs must have effective procedures to monitor utilization and to control cost of basic and supplemental health services and to achieve utilization goals, which may include mechanisms such as risk sharing, financial incentives, or other provisions agreed to by providers.

(c) Paragraph (a) of this section does not apply to the provision of the services of a physician:

(1) Which the HMO determines are unusual or infrequently used services; or

(2) Which, because of an emergency, it was medically necessary to provide to the enrollee other than as required by paragraph (a) of this section; or

(3) Which are provided as part of the inpatient hospital services by employees or staff of a hospital or provided by staff of other entities such as community mental health centers, home health agencies, visiting nurses' associations, independent laboratories, or family planning agencies.

(d) Supplemental health services must be provided or arranged for by the HMO and need not be provided by providers of basic health services under contract with the HMO.

(e) Each HMO must:

(1) Pay the provider, or reimburse its enrollees for the payment of reasonable charges for basic health services (or supplemental health services that the HMO agreed to provide on a prepayment basis) for which its enrollees have contracted, which were medically necessary and immediately required to be obtained other than through the HMO because of an unforeseen illness, injury, or condition, as determined by the HMO;

(2) Adopt procedures to review promptly all claims from enrollees for reimbursement for the provision of health services described in paragraph (e)(1) of this section, including a procedure for the determination of the medical necessity for obtaining the services other than through the HMO; and

(3) Provide instructions to its enrollees on procedures to be followed to secure these health services.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980; 45 FR 77031, Nov. 21, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6174, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§ 417.104 Payment for basic health services.

(a) *Basic health services payment.* Each HMO must provide or arrange for the provision of basic health services for a basic health services payment that:

(1) Is to be paid on a periodic basis without regard to the dates these services are provided;

(2) Is fixed without regard to the frequency, extent, or kind of basic health services actually furnished;

(3) Except as provided in paragraph (c) of this section, is fixed under a community rating system, as described in paragraph (b) of this section; and

(4) May be supplemented by nominal copayments which may be required for the provision of specific basic health services. Each HMO may establish one or more copayment options calculated on the basis of a community rating system.

(i) An HMO may not impose copayment charges that exceed 50 percent of the total cost of providing any single service to its enrollees, nor in the aggregate more than 20 percent of the total cost of providing all basic health services.

(ii) To insure that copayments are not a barrier to the utilization of health services or enrollment in the HMO, an HMO may not impose copayment charges on any subscriber (or enrollees covered by the subscriber's contract with the HMO) in any calendar year, when the copayments made by the subscriber (or enrollees) in that calendar year total 200 percent of the total annual premium cost which that

subscriber (or enrollees) would be required to pay if he (or they) were enrolled under an option with no copayments. This limitation applies only if the subscriber (or enrollees) demonstrates that copayments in that amount have been paid in that year.

(b) *Community rating system.* Under a community rating system, rates of payment for health services may be determined on a per person or per family basis, as described in paragraph (b)(1) of this section or on a per group basis as described in paragraph (b)(2) of this section. An HMO may fix its rates of payment under the system described in paragraph (b)(1) or (b)(2) of this section or under both such systems, but an HMO may use only one such system for fixing its rates of payment for any one group.

(1) A system of fixing rates of payment for health services may provide that the rates will be fixed on a per person or per family basis and may vary with the number of persons in a family. Except as otherwise authorized in this paragraph, these rates must be equivalent for all individuals and for all families of similar composition. Rates of payment may be based on either a schedule of rates charged to each subscriber group or on a per-enrollee-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In the former event, rates may vary from group to group if the projected total revenue from each group is substantially equivalent to the revenue that would be derived if the schedule of rates were uniform for all groups. In the latter event, the payments from each group of subscribers must be calculated to yield revenues substantially equivalent to the product of the total number of enrollees (or subscribers) expected to be enrolled from the group and the per-enrollee-per-month (or per-subscriber-per-month) revenue requirement for the HMO. Under the system described in this paragraph, rates of payment may not vary because of actual or anticipated utilization of services by individuals associated with any specific group of subscribers. These provisions do not preclude changes in the rates of payment that are established for new enrollments or re-enrollments and that do not apply to existing contracts until the renewal of these contracts.

(2) A system of fixing rates of payment for health services may provide that the rates will be fixed for individuals and families by groups. Except as otherwise authorized in this paragraph, such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If an HMO is to fix rates of payment for individuals and families by groups, it must:

(i) Classify all of the enrollees of the organization into classes based on factors that the HMO determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by CMS,

(ii) Determine its revenue requirements for providing services to the enrollees of each class established under paragraph (b)(2)(i) of this section, and

(iii) Fix the rates of payment for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under paragraph (b)(2)(ii) of this section for providing services to them as members of the classes established under paragraph (b)(2)(i) of this section. CMS will review the factors used by each HMO to establish classes under paragraph (b)(2)(i) of this section. If CMS determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, CMS will disapprove the factor for that purpose.

(3)(i) Nominal differentials in rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of potential subscribers:

(A) Individual (non-group) subscribers (including their families).

(B) Small groups of subscribers (100 subscribers or fewer).

(C) Large groups of subscribers (over 100 subscribers).

(ii) Differentials in rates may be established for subscribers enrolled in an HMO: (A) Under a contract with a governmental authority under section 1079 (''Contracts for Medical Care for

Spouses and Children: Plans'') or section 1086 (''Contracts for Health Benefits for Certain Members, Former Members and their Dependents'') of title 10 (''Armed Forces''), United States Code; or (B) under any other governmental program (other than the health benefits program authorized by chapter 89 (''Health Insurance'') of title 5 (''Government Organization and Employees''), United States Code; or (C) under any health benefits program for employees of States, political subdivisions of states, and other public entities.

(4) An HMO may establish a separate community rate for separate regional components of the organization upon satisfactory demonstration to CMS of the following:

(i) Each regional component is geographically distinct and separate from any other regional component; and

(ii) Each regional component provides substantially the full range of basic health services to its enrollees, without extensive referral between components of the organization for these services, and without substantial utilization by any two components of the same health care facilities. The separate community rate for each regional component of the HMO must be based on the different costs of providing health services in the respective regions.

(c) *Exceptions to community rating requirement*. (1) In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the requirement of community rating shall not apply to the HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(2) The requirement of community rating does not apply to the basic health services payment for basic health services provided an enrollee who is a full-time student at an accredited institution of higher education.

(d) *Late payment penalty*. HMOs may charge a late payment penalty on accounts receivable that are in arrears.

(e) *Review procedures for evaluating the community rating by class system under paragraph (b)(2).*[1] An HMO may establish a community rating system under paragraph (b)(2) of this section or revised factors used to establish classes after it receives written approval of the factors from CMS. CMS will give approval if it concludes that the factors can reasonably be used to predict the use of health services by individuals and families.

(1) An HMO must make a written request to CMS, listing the factors to be used in the community rating by class system under paragraph (b)(2) of this section.

(2) CMS will notify each HMO within 30 days of receipt of the request and application of one of the following:

(i) The application is approved;

(ii) Additional information or data are required and CMS will notify the HMO of its decision within 30 days from the date of receipt of this information or data; or

(iii) CMS needs additional time to review the written request and the HMO will be notified of CMS's decision within 90 days.

(Approved by the Office of Management and Budget under control number 0915–0051)

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38082, 38083, July 15, 1993]

§ 417.105 Payment for supplemental health services.

(a) An HMO may require supplemental health services payments, in addition to the basic health services payments, for the provision of each health service included in the supplemental health services set forth in § 417.102 for which subscribers have contracted, or it may include supplemental health services in the basic health services provided its enrollees for a basic health services payment.

[1] Further information entitled ''Guidelines for Rating by Class'' may be obtained from the Office of Prepaid Health Care, Division of Qualification Analysis, HHS Cohen Bldg., room 4360, 330 Independence Ave. SW., Washington, DC 20201.

(b) Supplemental health services payments may be made in any agreed upon manner, such as prepayment or fee-for-service. Supplemental health services payments that are fixed on a prepayment basis, however, must be fixed under a community rating system, unless the supplemental health services payment is for a supplemental health service provided an enrollee who is a full-time student at an accredited institution of higher education. In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualifed HMO, the community rating requirement shall not apply to that HMO during the forty-eight month period beginning with the month following the month in which it became a qualifed HMO.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17)

[45 FR 72528, Oct. 31, 1980, as amended at 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§417.106 Quality assurance program; Availability, accessibility, and continuity of basic and supplemental health services.

(a) *Quality assurance program.* Each HMO or CMP must have an ongoing quality assurance program for its health services that meets the following conditions:

(1) Stresses health outcomes to the extent consistent with the state of the art.

(2) Provides review by physicians and other health professionals of the process followed in the provision of health services.

(3) Uses systematic data collection of performance and patient results, provides interpretation of these data to its practitioners, and institutes needed change.

(4) Includes written procedures for taking appropriate remedial action whenever, as determined under the quality assurance program, inappropriate or substandard services have been provided or services that ought to have been furnished have not been provided.

(b) *Availability and accessibility of health care services.* Basic health services and those supplemental health services for which enrollees have contracted must be provided or arranged for by the HMO in accordance with the following rules:

(1) Except as provided in paragraph (b)(2) of this section, the services must be available to each enrollee within the HMO's service area.

(2) *Exception.* If the HMO's service area is located wholly within a nonmetropolitan area, the HMO may make available outside its service area any basic health service that is not a primary care or emergency care service, if the number of providers of that basic health service who will provide the service to the HMO's enrollees is insufficient to meet the demand. As used in this paragraph, primary care includes general practice, family practice, general internal medicine, general pediatrics, and general obstetrics and gynecology. An HMO that provides the services covered by these fields through at least a general or family practitioner, or a pediatrician and a general internist, is considered to be providing primary care.

(3) The services must be available and accessible with reasonable promptness to each of the HMO's enrollees as ensured through—

(i) Staffing patterns within generally accepted norms for meeting the projected enrollment needs; and

(ii) Geographic location, hours of operation, and arrangements for after-hours services. (Medically necessary emergency services must be available 24 hours a day, 7 days a week.)

(c) Continuity of care. The HMO must ensure continuity or care through arrangements that include but are not limited to the following:

(1) Use of a health professional who is primarily responsible for coordinating the enrollee's overall health care.

(2) A system of health and medical records that accumulates pertinent information about the enrollee's health care and makes it available to appropriate professionals.

(3) Arrangements made directly or through the HMO's providers to ensure that the HMO or the health professional who coordinates the enrollee's

overall health care is kept informed about the services that the referral resources furnish to the enrollee.

(d) *Confidentiality of health records.* Each HMO must establish adequate procedures to ensure the confidentiality of the health and medical records of its enrollees.

[58 FR 38068, July 15, 1993]

Subpart C—Qualified Health Maintenance Organizations: Organization and Operation

SOURCE: 58 FR 38068, July 15, 1993, unless otherwise noted.

§ 417.120 Fiscally sound operation and assumption of financial risk.

(a) *Fiscally sound operation*—(1) *General requirements.* Each HMO must have a fiscally sound operation, as demonstrated by the following:

(i) Total assets greater than total unsubordinated liabilities. In evaluating assets and liabilities, loan funds awarded or guaranteed under section 1306 of the PHS Act are not included as liabilities.

(ii) Sufficient cash flow and adequate liquidity to meet obligations as they become due.

(iii) A net operating surplus, or a financial plan that meets the requirements of paragraph (a)(2) of this section.

(iv) An insolvency protection plan that meets the requirements of § 417.122(b) for protection of enrollees.

(v) A fidelity bond or bonds, procured and maintained by the HMO, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the HMO.

(vi) Insurance policies or other arrangements, secured and maintained by the HMO and approved by CMS to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(2) *Financial plan requirement.* (i) If an HMO has not earned a cumulative net operating surplus during the three most recent fiscal years, did not earn a net operating surplus during the most recent fiscal year or does not have positive net worth, the HMO must submit a financial plan satisfactory to CMS to achieve net operating surplus within available fiscal resources.

(ii) This plan must include—

(A) A detailed marketing plan;

(B) Statements of revenue and expense on an accrual basis;

(C) Sources and uses of funds statements; and

(D) Balance sheets.

(b) *Assumption of financial risk.* Each HMO must assume full financial risk on a prospective basis for the provision of basic health services, except that it may obtain insurance or make other arrangements as follows:

(1) For the cost of providing to any enrollee basic health services with an aggregate value of more than $5,000 in any year.

(2) For the cost of basic health services obtained by its enrollees from sources other than the HMO because medical necessity required that they be furnished before they could be secured through the HMO.

(3) For not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for that fiscal year.

(4) For physicians or other health professionals, health care institutions, or any other combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for their furnishing of basic health services to the HMO's enrollees.

§ 417.122 Protection of enrollees.

(a) *Liability protection.* (1) Each HMO must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the HMO. These arrangements may include any of the following:

(i) Contractual arrangements that prohibit health care providers used by the enrollees from holding any enrollee liable for payment of any fees that are the legal obligation of the HMO.

(ii) Insurance, acceptable to CMS.

(iii) Financial reserves, acceptable to CMS, that are held for the HMO and restricted for use only in the event of insolvency.

(iv) Any other arrangements acceptable to CMS.

(2) The requirements of this paragraph do not apply to an HMO if CMS determines that State law protects the HMO enrollees from liability for payment of any fees that are the legal obligation of the HMO.

(b) *Protection against loss of benefits if the HMO becomes insolvent.* The insolvency protection plan required under §417.120(a) must provide for continuation of benefits as follows:

(1) For all enrollees, for the duration of the contract period for which payment has been made.

(2) For enrollees who are in an inpatient facility on the date of insolvency, until they are discharged from the facility.

§417.124 Administration and management.

(a) *General requirements.* Each HMO must have administrative and managerial arrangements satisfactory to CMS, as demonstrated by at least the following:

(1) A policymaking body that exercises oversight and control over the HMO's policies and personnel to ensure that management actions are in the best interest of the HMO and its enrollees.

(2) Personnel and systems sufficient for the HMO to organize, plan, control and evaluate the financial, marketing, health services, quality assurance program, administrative and management aspects of the HMO.

(3) At a minimum, management by an executive whose appointment and removal are under the control of the HMO's policymaking body.

(b) *Full and fair disclosure*—(1) *Basic rule.* Each HMO must prepare a written description of the following:

(i) Benefits (including limitations and exclusions).

(ii) Coverage (including a statement of conditions on eligibility for benefits).

(iii) Procedures to be followed in obtaining benefits and a description of circumstances under which benefits may be denied.

(iv) Rates.

(v) Grievance procedures.

(vi) Service area.

(vii) Participating providers.

(viii) Financial condition including at least the following most recently audited information: Current assets, other assets, total assets; current liabilities, long term liabilities; and net worth.

(2) *Requirements for the description.* (i) The description must be written in a way that can be easily understood by the average person who might enroll in the HMO.

(ii) The description of benefits and coverage may be in general terms if reference is made to a detailed statement of benefits and coverage that is available without cost to any person who enrolls in the HMO or to whom the opportunity for enrollment is offered.

(iii) The HMO must provide the description to any enrollee or person who is eligible to elect the HMO option and who requests the material from the HMO or the administrator of a health benefits plan. For purposes of this requirement, ''administrator'' (of a health benefits plan) has the meaning it is given in the Employment Retirement Income Security Act of 1974 (ERISA) at 29 U.S.C. 1002(16)(A).

(iv) If the HMO provides health services through individual practice associations (IPAs), the HMO must specify the number of member physicians by specialty, and a listing of the hospitals where HMO enrollees will receive basic and supplemental health services.

(v) If the HMO provides health services other than through IPAs, the HMO must specify, for each ambulatory care facility, the facility's address, days and hours of operation, and the number of physicians by specialty, and a listing of the hospitals where HMO enrollees will receive basic and supplemental health services.

(c) *Broadly representative enrollment.* (1) Each HMO must offer enrollment to persons who are broadly representative of the various age, social, and income groups within its service area.

(2) If an HMO has a medically underserved population located in its service area, not more than 75 percent of its

enrollees may be from the medically underserved population unless the area in which that population resides is a rural area.

(d) *Health status and enrollment.* (1) The HMO may not, on the basis of health status, health care needs, or age of the individual—

(i) Expel or refuse to reenroll any enrollee; or

(ii) Refuse to enroll individual members of a group.

(2) For purposes of this paragraph, a ''group'' is composed of individuals who enroll in the HMO under a contract or other arrangement that covers two or more subscribers. Examples of groups are employees who enroll under a contract between their employer and the HMO, or members of an organization that arranges coverage for its membership.

(3) Nothing in this subpart prohibits an HMO from requiring that, as a condition for continued eligibility for enrollment, enrolled dependent children, upon reaching a specified age, convert to individual enrollment, consistent with paragraph (e) of this section.

(e) *Conversion of enrollment.* (1) Each HMO must offer individual enrollment to the following:

(i) Each enrollee (and his or her enrolled dependents) leaving a group.

(ii) Each enrollee who would otherwise cease to be eligible for HMO enrollment because of his or her age, or the death or divorce of an enrollee.

(2) The individual enrollment offered must meet the conditions of subpart B of this part and this subpart C.

(3) The HMO is not required to offer individual enrollment except to the enrollees specified in this paragraph.

(4) The HMO must offer the enrollment on the same terms and conditions that it makes available to other nongroup enrollees.

(f) [Reserved]

(g) *Grievance procedures.* Each HMO must have and use meaningful procedures for hearing and resolving grievances between the HMO's enrollees and the HMO, including the HMO staff and medical groups and IPAs that furnish services. These procedures must ensure that:

(1) Grievances and complaints are transmitted in a timely manner to appropriate HMO decisionmaking levels that have authority to take corrective action; and

(2) Appropriate action is taken promptly, including a full investigation if necessary and notification of concerned parties as to the results of the HMO's investigation.

(h) *Certification of institutional providers.* Each HMO must ensure that its affiliated institutional providers meet one of the following conditions:

(1) In the case of hospitals, are either accredited by the Joint Commission on Accreditation of Health Care Organizations, or certified by Medicare.

(2) In the case of laboratories, are either CLIA-exempt, or have in effect a valid certificate of one of the following types, issued by CMS in accordance with section 353 of the PHS Act and part 493 of this chapter:

(i) Registration certificate.

(ii) Certificate.

(iii) Certificate of waiver.

(iv) Certificate of accreditation.

(3) In the case of other affiliated institutional providers, are certified for participation in Medicare and Medicaid in accordance with part 405, 416, 418, 488, or 491 of this chapter, as appropriate.

[58 FR 38068, July 15, 1993, as amended at 59 FR 49843, Sept. 30, 1994]

§ 417.126 Recordkeeping and reporting requirements.

(a) *General reporting and disclosure requirements.* Each HMO must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the HMO has a fiscally sound operation.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each HMO must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in paragraph (c) of this section) between the HMO and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the HMO and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the HMO go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the HMO.

(c) *''Significant business transaction'' defined.* As used in paragraph (b) of this section—

(1) Business transaction means any of the following kinds of transactions:

(i) Sale, exchange or lease of property.

(ii) Loan of money or extension of credit.

(iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

(2) *Significant business transaction* means any business transaction or series of transactions of the kind specified in paragraph (c)(1) of this section that, during any fiscal year of the HMO, have a total value that exceeds $25,000 or 5 percent of the HMO's total operating expenses, whichever is less.

(d) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the HMO and each of these parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(4) Upon written request from an HMO showing good cause, CMS may waive the requirement that its combined financial statement include the financial information required in this paragraph (d) with respect to a particular entity.

(e) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an HMO in its offerings, the HMO must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular HMO) under the Employee Retirement Income Security Act of 1974 (ERISA).

(i) The HMO must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(ii) Loan of money or extension of credit.

(iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

(2) *Significant business transaction* means any business transaction or series of transactions of the kind specified in paragraph (c)(1) of this section that, during any fiscal year of the

HMO, have a total value that exceeds $25,000 or 5 percent of the HMO's total operating expenses, whichever is less.

(d) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the HMO and each of these parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) These statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes.

(4) Upon written request from an HMO showing good cause, CMS may waive the requirement that its combined financial statement include the financial information required in this paragraph (d) with respect to a particular entity.

(e) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an HMO in its offerings, the HMO must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular HMO) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The HMO must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

Subpart D—Application for Federal Qualification

§ 417.140 Scope.

This subpart sets forth—

(a) The requirements for—

(1) Entities that seek qualification as HMOs under title XIII of the PHS Act; and

(2) HMOs that seek—

(i) Qualification for their regional components; or

(ii) Expansion of their service areas;

(b) The procedures that CMS follows to make determinations; and

(c) Other related provisions, including application fees.

[59 FR 49836, Sept. 30, 1994]

§ 417.142 Requirements for qualification.

(a) *General rules.* (1) An entity seeking qualification as an HMO must meet the requirements and provide the assurances specified in paragraphs (b) through (f) of this section, as appropriate.

(2) CMS determines whether the entity is an HMO on the basis of the entity's application and any additional information and investigation (including site visits) that CMS may require.

(3) CMS may determine that an entity is any of the following:

(i) An operational qualified HMO.

(ii) A preoperational qualified HMO.

(iii) A transitional qualified HMO.

(b) *Operational qualified HMO.* CMS determines that an entity is an operational qualified HMO if—

(1) CMS finds that the entity meets the requirements of subparts B and C of this part.

(2) The entity, within 30 days of CMS's determination, provides written assurances, satisfactory to CMS, that it—

(i) Provides and will provide basic health services (and any supplemental health services included in any contract) to its enrollees;

(ii) Provides and will provide these services in the manner prescribed in sections 1301(b) and 1301(c) of the PHS Act and subpart B of this part;

(iii) Is organized and operated and will continue to be organized and operated in the manner prescribed in section 1301(c) of the PHS Act and subpart C of this part;

(iv) Under arrangements that safeguard the confidentiality of patient information and records, will provide access to CMS and the Comptroller General or any of their duly authorized representatives for the purpose of audit, examination or evaluation to any books, documents, papers, and records of the entity relating to its operation as an HMO, and to any facilities that it operates; and

(v) Will continue to comply with any other assurances that it has given to CMS.

(c) *Preoperational qualified HMO.* (1) CMS may determine that an entity is a

preoperational qualified HMO if it provides, within 30 days of CMS's determination, satisfactory assurances that it will become operational within 60 days following that determination and will, when it becomes operational, meet the requirements of subparts B and C of this part.

(2) Within 30 days after receiving notice that the entity has begun operation, CMS determines whether it is an operational qualified HMO. In the absence of this determination, the entity is not an operational qualified HMO even though it becomes operational.

(d) *Transitional qualified HMO: General rules*—(1) *Basic requirements.* CMS may determine that an entity is a transitional qualified HMO if the entity—

(i) Meets the requirements of paragraph (d)(2) through (d)(4) of this section; and

(ii) Provides the assurances specified in paragraphs (d)(5) through (d)(7) of this section within 30 days of CMS's determination.

(2) *Organization and operation.* The entity is organized and operated in accordance with subpart C of this part, except that it need not—

(i) Assume full financial risk for the provision of basic health services as required by §417.120(b); or

(ii) Comply with the limitations that are imposed on insurance by §417.120(b)(1).

(3) *Range of services.* The entity is currently providing the following services on a prepaid basis:

(i) Physician services.

(ii) Outpatient services and inpatient hospital services. (The entity need not provide or pay for hospital inpatient or outpatient services that it can show are being provided directly, through insurance, or under arrangements, by other entities.)

(iii) Medically necessary emergency services.

(iv) Diagnostic laboratory services and diagnostic and therapeutic radiologic services.

These services must meet the requirement of §417.101, but may be limited in time and cost without regard to the constraints imposed by §417.101(a).

(4) *Payment for services*—(i) *General rule.* The entity pays for basic health services in accordance with §417.104, except that it need not comply with the copayments limitations imposed by §417.104(a)(4).

(ii) *Determination of payment rates.* In determining payment rates, the entity need not comply with the community rating requirements of §§417.104(b) and 417.105(b).

(5) *Contracts in effect on the date of CMS's determination.* The entity gives assurances that it will meet the following conditions with respect to its group and individual contracts that are in effect on the date of CMS's determination, and which are renewed or renegotiated during the period approved by CMS under paragraph (d)(6) of this section:

(i) Continue to provide services in accordance with paragraph (d)(3) of this section.

(ii) Continue to be organized and operated and to pay for basic health services in accordance with paragraphs (d)(2) and (d)(4) of this section, respectively.

(6) *Time-phased plan.* The entity gives assurances as follows:

(i) It will implement a time-phased plan acceptable to CMS that—

(A) May not extend for more than 3 years from the date of CMS's determination; and

(B) Specifies definite steps for meeting, at the time of renewal of each group or individual contract, all the requirements of subparts B and C of this part.

(ii) Upon completion of this time-phased plan, it will—

(A) Provide basic and supplemental services to all of its enrollees; and

(B) Be organized and operated, and provide services, in accordance with subparts B and C of this part.

(7) *Contracts entered into after the date of CMS's determination.* The entity gives assurances that, with respect to any group or individual contract entered into after the date of CMS's determination, it will—

(i) Be organized and operated in accordance with subpart C of this part; and

(ii) Provide basic health services and any supplemental health services included in the contract, in accordance with subpart B of this part.

(e) *Failure to sign assurances timely.* If CMS determines that an entity meets the requirements for qualification and the entity fails to sign its assurances within 30 days following the date of the determination, CMS gives the entity written notice that its application is considered withdrawn and that it is not a qualified HMO.

(f) *Qualification of regional components.* An HMO that has more than one regional component is considered qualified for those regional components for which assurances have been signed in accordance with this section.

(g) *Special rules: Enrollees entitled to Medicare or Medicaid.* For an HMO that accepts enrollees entitled to Medicare or Medicaid, the following rules apply:

(1) The requirements of titles XVIII and XIX of the Act, as appropriate, take precedence over conflicting requirements of sections 1301(b) and 1301(c) of the PHS Act.

(2) The HMO must, with respect to its enrollees entitled to Medicare or Medicaid, comply with the applicable requirement of title XVIII or XIX, including those that pertain to—

(i) Deductibles and coinsurance;

(ii) Enrollment mix and enrollment practices;

(iii) State plan rules on copayment options; and

(iv) Grievance procedures.

(3) An HMO that complies with paragraph (g)(2) of this section may obtain and retain Federal qualification if, for its other enrollees, the HMO meets the requirements of sections 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and in subparts B and C of this part.

(h) *Special rules: Enrollees under the Federal employee health benefits program (FEHBP).* An HMO that accepts enrollees under the FEHBP (Chapter 89 of title 5 of the U.S.C.) may obtain and retain Federal qualification if, for its other enrollees, it complies with the requirements of section 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and subparts B and C of this part.

[59 FR 49836, Sept. 30, 1994]

§ 417.143 Application requirements.

(a) *General requirements.* This section sets forth application requirements for entities that seek qualification as HMOs; HMOs that seek expansion of their service areas; and HMOs that seek qualification of their regional components as HMOs.

(b) *Completion of an application form.* (1) In order to receive a determination concerning whether an entity is a qualified HMO, an individual authorized to act for the entity (the applicant) must complete an application form provided by CMS.

(2) The authorized individual must describe thoroughly how the entity meets, or will meet, the requirements for qualified HMOs described in the PHS Act and in subparts B and C of this part, this subpart D, and 417.168 and 417.169 of subpart F.

(c) *Collection of an application fee.* In accordance with the requirements of 31 U.S.C. 9701, Fees and charges for Government services and things of value, CMS determines the amount of the application fee that must be submitted with each type of application.

(1) The fee is reasonably related to the Federal government's cost of qualifying an entity and may vary based on the type of application.

(2) Each type of application has one set fee rather than a charge based on the specific cost of each determination. (For example, each Federally qualified HMO applicant seeking Federal qualification of one of its regional components as an HMO is charged the same amount, unless the amount of the fee has been changed under paragraph (f) of this section.)

(d) *Application fee amounts.* The application fee amounts for applications completed on or after July 13, 1987 are as follows:

(1) $18,400 for an entity seeking qualification as an HMO or qualification of a regional component of an HMO.

If, in the case of an HMO seeking qualification of a regional component, CMS determines that there is no need for a site visit, $8,000 will be returned to the applicant.

(2) $6,900 for an HMO seeking expansion of its service area.

(3) $3,100 for a CMP seeking qualification as an HMO.

(e) *Refund of an application fee.* CMS refunds an application fee only if the entity withdraws its application within

10 working days after receipt by CMS. Application fees are not returned in any other circumstance, even if qualification or certification is denied.

(f) *Procedure for changing the amount of an application fee.* If CMS determines that a change in the amount of a fee is appropriate, CMS issues a notice of proposed rulemaking in the FEDERAL REGISTER to announce the proposed new amount.

(g) *New application after denial.* An entity may not submit another application under this subpart for the same type of determination for four full months after the date of the notice in which CMS denied the application.

(h) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5, the Department's regulations providing exceptions to disclosure, should label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5.

[52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38077, July 15, 1993]

§417.144 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an application for Federal qualification on the basis of information contained in the application itself and any additional information that CMS obtains through onsite visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, CMS notifies the entity and allows 60 days from the date of the notice for the entity to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the entity meets the applicable requirements of §§417.142 and 417.143.

(b) *Notice of determination.* CMS notifies each entity that applies for qualification under this subpart of its determination and the basis for the determination. The determination may be granting of qualification, intent to deny, or denial.

(c) *Intent to deny.* (1) If CMS finds that the entity does not appear to meet the requirements for qualification and appears to be able to meet those requirements within 60 days, CMS gives the entity notice of intent to deny qualification and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the entity may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding, and may revise its application to remedy any defects identified by CMS.

(d) *Denial and reconsideration of denial.* (1) If CMS denies an application for qualification under this subpart, CMS gives the entity written notice of the denial and an opportunity to request reconsideration of that determination.

(2) A request for reconsideration must—

(i) Be submitted in writing, within 60 days following the date of the notice of denial;

(ii) Be addressed to the CMS officer or employee who denied the application; and

(iii) Set forth the grounds upon which the entity requests reconsideration, specifying the material issues of fact and of law upon which the entity relies.

(3) CMS bases its reconsideration upon the record compiled during the qualification review proceedings, materials submitted in support of the request for reconsideration, and other relevant materials available to CMS.

(4) CMS gives the entity written notice of the reconsidered determination and the basis for the determination.

(e) *Information on qualified HMOs*—(1) FEDERAL REGISTER *notices.* In quarterly FEDERAL REGISTER notices, CMS gives the names, addresses, and service areas of newly qualified HMOs and describes the expanded service areas of other qualified HMOs.

(2) *Listings.* A cumulative list of qualified HMOs is available from the following office, which is open from 8:30 a.m. to 5 p.m., Monday through Friday: Office of Managed Care, room 4360,

Cohen Building, 400 Independence Avenue SW., Washington, DC 20201.

[59 FR 49837, Sept. 30, 1994]

Subpart E—Inclusion of Qualified Health Maintenance Organizations in Employee Health Benefits Plans

SOURCE: 45 FR 72517, Oct. 31, 1980, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§ 417.150 Definitions.

As used in this subpart, unless the context indicates otherwise—

Agreement means a collective bargaining agreement.

Bargaining representative means an individual or entity designated or selected, under any applicable Federal, State, or local law, or public entity collective bargaining agreement, to represent employees in collective bargaining, or any other employee representative designated or selected under any law.

Carrier means a voluntary association, corporation, partnership, or other organization that is engaged in providing, paying for, or reimbursing all or part of the cost of health benefits under group insurance policies or contracts, medical or hospital service agreements, enrollment or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier.

Collective bargaining agreement means an agreement entered into between an employing entity and the bargaining representative of its employees.

Contract means an employer-employee or public entity-employee contract, or a contract for health benefits.

Designee means any person or entity authorized to act on behalf of an employing entity or a group of employing entities to offer the option of enrollment in a qualified health maintenance organization to their eligible employees.

Eligible employee means an employee who meets the employer's requirements for participation in the health benefits plan.

Employee means any individual employed by an employer or public entity on a full-time or part-time basis.

Employer has the meaning given that term in section 3(d) of the Fair Labor Standards Act of 1938, except that it—

(1) Includes non-appropriated fund instrumentalities of the United States Government; and

(2) Excludes the following:

(i) The governments of the United States, the District of Columbia and the territories and possessions of the United States, the 50 States and their political subdivisions, and any agencies or instrumentalities of any of the foregoing, including the United States Postal Service and Postal Rate Commission.

(ii) Any church, or convention or association of churches, and any organization operated, supervised, or controlled by a church, or convention or association of churches that meets the following conditions:

(A) Is an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Does not discriminate, in the employment, compensation, promotion or termination of employment of any personnel, or in the granting of staff and other privileges to physicians or other health personnel, on the grounds that the individuals obtain health care through HMOs, or participate in furnishing health care through HMOs.

Employing entity means an employer or public entity.

Employing entity-employee contract means a legally enforceable agreement (other than a collective bargaining agreement) between an employing entity and its employees for the provision of, or payment for, health benefits for its employees, or for its employees and their eligible dependents.

Group enrollment period means the period of at least 10 working days each calendar year during which each eligible employee is given the opportunity to select among the alternatives included in a health benefits plan.

Health benefits means health benefits and services.

Health benefits contract means a contract or other agreement between an employing entity or a designee and a carrier for the provision of, or payment

for, health benefits to eligible employees or to eligible employees and their eligible dependents.

Health benefits plan means any arrangement, to provide or pay for health services, that is offered to eligible employees, or to eligible employees and their eligible dependents, by or on behalf of an employing entity.

Public entity means the 50 states, Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands and American Samoa and their political subdivisions, the District of Columbia, and any agency or instrumentality of the foregoing, and *political subdivisions* include counties, parishes, townships, cities, municipalities, towns, villages, and incorporated villages.

Qualified HMO means an HMO that has in effect a determination, made under subpart D of this part, that the HMO is an operational, preoperational, or transitional qualified HMO.

To offer a health benefits plan means to make participation in a health benefits plan available to eligible employees, or to eligible employees and their eligible dependents regardless of whether the employing entity makes a financial contribution to the plan on behalf of these employees, directly or indirectly, for example, through payments on any basis into a health and welfare trust fund.

[45 FR 72517, Oct. 31, 1980, as amended at 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38077, July 15, 1993; 59 FR 49837, 49843, Sept. 30, 1994]

§417.151 Applicability.

(a) *Basic rule*. Effective October 24, 1995,[1] this subpart applies to any employing entity that offers a health benefits plan to its employees, meets the conditions specified in paragraphs (b) through (e) of this section, and elects to include one or more qualified HMOs in the health plan alternatives it offers its employees.

(b) *Number of employees*. During any calendar quarter of the preceding calendar year, the employer or public entity employed an average of not less than 25 employees.

(c) *Minimum wage*. During any calendar quarter of the preceding calendar year, the employer was required to pay the minimum wage specified in section 6 of the Fair Labor Standards Act of 1938, or would have been required to pay that wage but for section 13(a) of that Act.

(d) *Federal assistance under section 317 of the PHS Act*. The public entity has a pending application for, or is receiving, assistance under section 317 of the PHS Act.

(e) *Employees in HMO's service area*. At least 25 of the employing entity's employees reside within the HMO's service area.

[59 FR 49838, Sept. 30, 1994, as amended at 61 FR 27287, May 31, 1996]

§417.153 Offer of HMO alternative.

(a) *Basic rule*. An employing entity that is subject to this subpart and that elects to include one or more qualified HMOs must offer the HMO alternative in accordance with this section.

(b) *Employees to whom the HMO option must be offered*. Each employing entity must offer the option of enrollment in a qualified HMO to each eligible employee and his or her eligible dependents who reside in the HMO's service area.

(c) *Manner of offering the HMO option*. (1) For employees who are represented by a bargaining representative, the option of enrollment in a qualified HMO—

(i) Must first be presented to the bargaining representative; and

(ii) If the representative accepts the option, must then be offered to each represented employee.

(2) For employees not represented by a bargaining representative, the option must be offered directly to those employees.

[59 FR 49839, Sept. 30, 1994, as amended at 61 FR 27287, May 31, 1996]

[1] Before October 24, 1995, an employing entity that met the conditions specified in §417.151 was required to include one or more qualified HMOs, if it received from at least one qualified HMO a written request for inclusion and that request met the timing, content, and procedural requirements specified in §417.152.

§ 417.155 How the HMO option must be included in the health benefits plan.

(a) *HMO access to employees*—(1) *Purpose and timing.*

(i) *Purpose.* The employing entity must provide each HMO included in its health benefits plan fair and reasonable access to all employees specified in § 417.153(b), so that the HMO can explain its program in accordance with § 417.124(b).

(ii) *Timing.* The employing entity must provide access beginning at least 30 days before, and continuing during, the group enrollment period.

(2) *Nature of access.* (i) Access must include, at a minimum, opportunity to distribute educational literature, brochures, announcements of meetings, and other relevant printed materials that meet the requirements of § 417.124(b).

(ii) Access may not be more restrictive or less favorable than the access the employing entity provides to other offerors of options included in the health benefits plan, whether or not those offerors elect to avail themselves of that access.

(b) *Review of HMO offering materials.* (1) The HMO must give the employing entity or designee opportunity to review, revise, and approve HMO educational and offering materials before distribution.

(2) Revisions must be limited to correcting factual errors and misleading or ambiguous statements, unless—

(i) The HMO and the employing entity agree otherwise; or

(ii) Other revisions are required by law.

(3) The employing entity or designee must complete revision of the materials promptly so as not to delay or otherwise interfere with their use during the group enrollment period.

(c) *Group enrollment period; prohibition of restrictions; effective date of HMO coverage*—(1) *Prohibition of restrictions.* If an employing entity or designee includes the option of enrollment in a qualified HMO in the health benefits plan offered to its eligible employees, it must provide a group enrollment period before the effective date of HMO coverage. The employing entity may not impose waiting periods as a condition of enrollment in the HMO or of transfer from HMO to non-HMO coverage, or exclusions, or limitations based on health status.

(2) *Effective date of coverage.* Unless otherwise agreed to by the employing entity, or designee, and the HMO, coverage under the HMO contract for employees selecting the HMO option begins on the day the non-HMO contract expires or is renewed without lapse.

(3) *Coordination of benefits.* Nothing in this subpart precludes the uniform application of coordination of benefits agreements between the HMOs and the other carriers that are included in the health benefits plan.

(d) *Continued eligibility for ''free-standing'' health benefits*—(1) *Basic requirement.* At the request of a qualified HMO, the employing entity or its designee must provide that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for free-standing dental, optical, or prescription drug benefits for which they were previously eligible or would be eligible if selecting a non-HMO option and that are not included in the services provided by the HMO to its enrollees as part of the HMO prepaid benefit package.

(2) *''Free-standing'' defined.* For purposes of this paragraph, the term ''free-standing'' refers to a benefit that—

(i) Is not integrated or incorporated into a basic health benefits package or major medical plan, and

(ii) Is—

(A) Offered by a carrier other than the one offering the basic health benefits package or major medical plan; or

(B) Subject to a premium separate from the premium for the basic health benefits package or major medical plan.

(3) *Examples of the employing entity's obligation with respect to the continued eligibility.* (i) The health benefits plan includes a free-standing dental benefit. The HMO does not offer any dental coverage as part of its health services provided to members on a prepaid basis. The employing entity must provide that employees who select the HMO option continue to be eligible for dental coverage. (If the dental coverage is not optional for employees selecting the

non-HMO option, nothing in this regulation requires that the coverage be made optional for employees selecting the HMO option. Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the non-HMO option.) -

(ii) The non-HMO option provides free-standing coverage for optical services (such as refraction and the provision of eyeglasses), and the HMO does not. The employing entity must provide that employees who select the HMO option continue to be eligible for optical coverage.

(iii) The non-HMO option includes dental coverage in its major medical package, with a common deductible applied to dental as well as non-dental benefits. The HMO provides no dental coverage as part of its pre-paid health services. Because the dental coverage is not free-standing, the employing entity is not required to provide that employees who select the HMO option continue to be eligible for dental coverage, but is free to do so.

(e) *Opportunity to select among coverage options: Requirement for affirmative written selection*—(1) *Opportunity other than during a group enrollment period.* The employing entity or designee must provide opportunity (in addition to the group enrollment period) for selection among coverage options, by eligible employees who meet any of the following conditions:

(i) Are new employees.

(ii) Have been transferred or have changed their place of residence, resulting in—

(A) Eligibility for enrollment in a qualified HMO for which they were not previously eligible by place of residence; or

(B) Residence outside the service area of a qualified HMO in which they were previously enrolled.

(iii) Are covered by any coverage option that ceases operation.

(2) *Prohibition of restrictions.* When the employees specified in paragraph (e)(1) of this section are eligible to participate in the health benefits plan, the employing entity or designee must make available, without waiting periods or exclusions based on health status as a condition, the opportunity to enroll in an HMO, or transfer from HMO coverage to non-HMO coverage.

(3) *Affirmative written selection.* The employing entity or designee must require that the eligible employee make an affirmative written selection in any of the following circumstances:

(i) Enrollment in a particular qualified HMO is offered for the first time.

(ii) The eligible employee elects to change from one option to another.

(iii) The eligible employee is one of those specified in paragraph (e)(1) of this section.

(f) *Determination of copayment levels and supplemental health services.* The selection of a copayment level and of supplemental health services to be contracted for must be made as follows:

(1) For employees represented by a collective bargaining representative, the selection of copayment levels and supplemental health services is subject to the collective bargaining process.

(2) For employees not represented by a bargaining representative, the selection of copayment levels and supplemental health services is subject to the same decisionmaking process used by the employing entity with respect to the non-HMO option in its health benefits plan.

(3) In all cases, the HMO has the right to include, with the basic benefits package it provides to its enrollees for a basic health services payment, on a non-negotiable basis, those supplemental health services that meet the following conditions:

(i) Are required to be offered under State law.

(ii) Are included uniformly by the HMO in its prepaid benefit package.

(iii) Are available to employees who select the non-HMO option but not available to those who select the HMO option.

[59 FR 49840, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

§417.156 When the HMO must be offered to employees.

(a) *General rules.* (1) The employing entity or designee must offer eligible employees the option of enrollment in a qualified HMO at the earliest date permitted under the terms of existing agreements or contracts.

(2) If the HMO's request for inclusion in a health benefits plan is received at a time when existing contracts or agreements do not provide for inclusion, the employing entity must include the HMO option in the health benefits plan at the time that new agreements or contracts are offered or negotiated.

(b) *Specific requirements.* Unless mutually agreed otherwise, the following rules apply:

(1) *Collective bargaining agreement.* The employing entity or designee must raise the HMO's request during the collective bargaining process—

(i) When a new agreement is negotiated;

(ii) At the time prescribed, in an agreement with a fixed term of more than 1 year, for discussion of change in health benefits; or

(iii) In accordance with a specific process for review of HMO offers.

(2) *Contracts.* For employees not covered by a collective bargaining agreement, the employing entity or designee must include the HMO option in any health benefits plan offered to eligible employees when the existing contract is renewed or when a new health benefits contract or other arrangement is negotiated.

(i) If a contract has no fixed term or has a term in excess of 1 year, the contract must be treated as renewable on its earliest anniversary date.

(ii) If the employing entity or designee is self-insured, the budget year must be treated as the term of the existing contract.

(3) *Multiple arrangements.* In the case of a health benefits plan that includes multiple contracts or other arrangements with varying expiration or renewal dates, the employing entity must include the HMO option, in accordance with paragraphs (b)(1) and (b)(2) of this section,—

(i) At the time each contract or arrangement is renewed or reissued; or

(ii) The benefits provided under the contract or arrangement are offered to employees.

[59 FR 49841, Sept. 30, 1994]

§ 417.157 Contributions for the HMO alternative.

(a) *General principles*—(1) *Nondiscrimination.* The employer contribution to an HMO must be in an amount that does not discriminate financially against an employee who enrolls in an HMO. A contribution does not discriminate financially if the method of determining the contribution is reasonable and is designed to ensure that employees have a fair choice among health benefits plan alternatives.

(2) *Effect of agreements or contracts.* The employing entity or designee is not required to pay more for health benefits as a result of offering the HMO alternative than it would otherwise be required to pay under a collective bargaining agreement or contract that provides for health benefits and is in effect at the time the HMO alternative is included.

(3) *Examples of acceptable employer contributions.* The following are methods that are considered nondiscriminatory:

(i) The employer contribution to the HMO is the same, per employee, as the contribution to non-HMO alternatives.

(ii) The employer contribution reflects the composition of the HMO's enrollment in terms of enrollee attributes that can reasonably be used to predict utilization, experience, costs, or risk. For each enrollee in a given class established on the basis of those attributes, the employer contributes an equal amount, regardless of the health benefits plan chosen by the employee.

(iii) The employer contribution is a fixed percentage of the premium for each of the alternatives offered.

(iv) The employer contribution is determined under a mutually acceptable arrangement negotiated by the HMO and the employer. In negotiating the arrangement, the employer may not insist on terms that would cause the HMO to violate any of the requirements of this part.

(4) *Adjustment of employer contribution.* An employer contribution determined by an acceptable method may in some cases be adjusted if it would result in a nominal payment or no payment at all by HMO enrollees (because the HMO premium is lower than the

premiums for the other alternatives offered). If, for example the employer has a policy of requiring all employees to contribute to their health benefits plan, the employer may require HMO enrollees who would otherwise pay little or nothing at all, to make a payment that does not exceed 50 percent of the employee contribution to the principal non-HMO alternative. The principal non-HMO alternative is the one that covers the largest number of enrollees from the particular employer.

(b) *Administrative expenses.* (1) In determining the amount of its contribution to the HMO, the employing entity or designee may not consider administrative expenses incurred in connection with offering any alternative in the health benefits plan.

(2) However, if the employing entity or designee has special requirements for other than standard solicitation brochures and enrollment literature, it must, in the case of the HMO alternative, determine and distribute any administrative costs attributable to those requirements in a manner consistent with its method of determining and distributing those costs for the non-HMO alternatives.

(c) *Exclusion for contribution for certain benefits.* In determining the amount of the employing entity's contribution or the designee's cost for the HMO alternative, the employing entity or designee may exclude those portions of the contribution allocable to benefits (such as life insurance or insurance for supplemental health benefits)—

(1) For which eligible employees and their eligible dependents are covered notwithstanding selection of the HMO alternative; and

(2) That are not offered on a prepayment basis by the HMO to the employing entity's employees.

(d) *Contributions determined by agreements or contracts or by law.* If the specific amount of the employing entity's contribution for health benefits is fixed by an agreement or contract, or by law, that amount constitutes the employing entity's obligation for contribution toward the HMO premiums.

(e) *Allocation of portion of a contribution determined by an agreement.* In some cases, the employing entity's contribution for health benefits is determined by an agreement that also provides for benefits other than health benefits. In that case, the employing entity must determine, or instruct its designee to determine, what portion of its contribution is applicable to health benefits.

(f) *Retention and availability of data.* Each employing entity or designee must retain the following data for three years and make it available to CMS upon request:

(1) The data used to compute the level of contribution for each of the plans offered to employees.

(2) Related data about the employees who are eligible to enroll in a plan.

(3) A description of the methodology for computation.

(g) *CMS review of data.* (1) CMS may request and review the data specified in paragraph (f) of this section on its own initiative or in response to requests from HMOs or employees.

(2) The purpose of CMS's review is to determine whether the methodology and the level of contribution comply with the requirements of this subpart.

(3) HMOs and employees that request CMS to review must set forth reasonable grounds for making the request.

[61 FR 27287, May 31, 1996]

§417.158 Payroll deductions.

Each employing entity that provides payroll deductions as a means of paying employees' contributions for health benefits or provides a health benefits plan that does not require an employee contribution must, with the consent of an employee who selects the HMO option, arrange for the employee's contribution, if any, to be paid through payroll deductions.

[59 FR 49841, Sept. 30, 1994]

§417.159 Relationship of section 1310 of the Public Health Service Act to the National Labor Relations Act and the Railway Labor Act.

The decision of an employing entity subject to this subpart to include the HMO alternative in any health benefits plan offered to its eligible employees must be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway

Labor Act, and other laws of similar effect.

[59 FR 49841, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

Subpart F—Continued Regulation of Federally Qualified Health Maintenance Organizations

SOURCE: 43 FR 32255, July 25, 1978, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

§ 417.160 Applicability.

This subpart applies to any entity that has been determined to be a qualified HMO under subpart D of this part.

[59 FR 49841, Sept. 30, 1994]

§ 417.161 Compliance with assurances.

Any entity subject to this subpart must comply with the assurances that it provided to CMS, unless compliance is waived under § 417.166.

[58 FR 38071, July 15, 1993]

§ 417.162 Reporting requirements.

Entities subject to this subpart must submit:

(a) The reports that may be required by CMS under § 417.126, and

(b) Any additional reports CMS may reasonably require.

[58 FR 38071, July 15, 1993]

§ 417.163 Enforcement procedures.

(a) *Complaints.* Any person, group, association, corporation, or other entity may file with CMS a written complaint with respect to an HMO's compliance with assurances it gave under subpart D of this part. A complaint must—

(1) State the grounds and underlying facts of the complaint;

(2) Give the names of all persons involved; and

(3) Assure that all appropriate grievance and appeals procedures established by the HMO and available to the complainant have been exhausted.

(b) *Investigations.* (1) CMS may initiate investigations when, based on a report, a complaint, or any other information, CMS has reason to believe that a Federally qualified HMO is not in compliance with any of the assurances it gave under subpart D of this part.

(2) When CMS initiates an investigation, it gives the HMO written notice that includes a full statement of the pertinent facts and of the matters being investigated and indicates that the HMO may submit, within 30 days of the date of the notice, a written report concerning these matters.

(3) CMS obtains any information it considers necessary to resolve issues related to the assurances, and may use site visits, public hearings, or any other procedures that CMS considers appropriate in seeking this information.

(c) *Determination and notice by CMS*—(1) *Determination.* (i) On the basis of the investigation, CMS determines whether the HMO has failed to comply with any of the assurances it gave under subpart D of this part.

(ii) CMS publishes in the FEDERAL REGISTER a notice of each determination of non-compliance.

(2) *Notice of determination: Corrective action.* (i) CMS gives the HMO written notice of the determination.

(ii) The notice specifies the manner in which the HMO has not complied with its assurances and directs the HMO to initiate the corrective action that CMS considers necessary to bring the HMO into compliance.

(iii) The HMO must initiate this corrective action within 30 days of the date of the notice from CMS, or within any longer period that CMS determines to be reasonable and specifies in the notice. The HMO must carry out the corrective action within the time period specified by CMS in the notice.

(iv) The notice may provide the HMO an opportunity to submit, for CMS's approval, proposed methods for achieving compliance.

(d) *Remedy: Revocation of qualification.* If CMS determines that a qualified HMO has failed to initiate or to carry out corrective action in accordance with paragraph (c)(2) of this section—(1) CMS revokes the HMO's qualification and notifies the HMO of this action.

(2) In the notice, CMS provides the HMO with an opportunity for reconsideration of the revocation, including, at the HMO's election, a fair hearing.

(3) The revocation of qualification is effective on the tenth calendar day

after the day of the notice unless CMS receives a request for reconsideration by that date.

(4) If after reconsideration CMS again determines to revoke the HMO's qualification, this revocation is effective on the tenth calendar day after the date of the notice of reconsidered determination.

(5) CMS publishes in the FEDERAL REGISTER each determination it makes under this paragraph (d).

(6) A revocation under this paragraph (d) has the effect described in §417.164.

(e) *Notice by the HMO*. Within 15 days after the date CMS issues a notice of revocation, the HMO must prepare a notice that explains, in readily understandable language, the reasons for the determination that it is not a qualified HMO, and send the notice to the following:

(1) The HMO's enrollees.

(2) Each employer or public entity that has offered enrollment in the HMO in accordance with subpart E of this part.

(3) Each lawfully recognized collective bargaining representative or other representative of the employees of the employer or public entity.

(f) *Reimbursement of enrollees for services improperly denied, or for charges improperly imposed*. (1) If CMS determines, under paragraph (c)(1) of this section, that an HMO is out of compliance, CMS may require the HMO to reimburse its enrollees for the following—

(i) Expenses for basic or supplemental health services that the enrollee obtained from other sources because the HMO failed to provide or arrange for them in accordance with its assurances.

(ii) Any amounts the HMO charged the enrollee that are inconsistent with its assurances. (Rules applicable to charges for all enrollees are set forth in §§417.104 and 417.105. The additional rules applicable to Medicare enrollees are in §415.454.)

(2) This paragraph applies regardless of when the HMO failed to comply with the appropriate assurances.

(g) *Remedy: Civil suit*—(1) *Applicability*. This paragraph applies to any HMO or other entity to which a grant, loan, or loan guarantee was awarded, as set forth in subpart V of this part, on the basis of its assurances regarding the furnishing of basic and supplemental services or its operation and organization, as the case may be.

(2) *Basis for action*. If CMS determines that the HMO or other entity has failed to initiate or refuses to carry out corrective action in accordance with paragraph (c)(2) of this section, CMS may bring civil action in the U.S. district court for the district in which the HMO or other entity is located, to enforce compliance with the assurances it gave in applying for the grant, loan, or loan guarantee.

[59 FR 49841, Sept. 30, 1994]

§417.164 Effect of revocation of qualification on inclusion in employee's health benefit plans.

When an HMO's qualification is revoked under §417.163(d), the following rules apply:

(a) The HMO may not seek inclusion in employees health benefits plans under subpart E of this part.

(b) Inclusion of the HMO in an employer's health benefits plan—

(1) Is disregarded in determining whether the employer is subject to the requirements of subpart E of this part; and

(2) Does not constitute compliance with subpart E of this part by the employer.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

§417.165 Reapplication for qualification.

An entity whose qualification as an HMO has been revoked by CMS for purposes of section 1310 of the PHS Act may, after completing the corrective action required under §417.163(c)(2), reapply for a determination of qualification in accordance with the procedures specified in subpart D of this part.

[43 FR 32255, July 25, 1978. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38078, July 15, 1993]

§417.166 Waiver of assurances.

(a) *General rule*. CMS may release an HMO from compliance with any assurances the HMO gives under subpart D of this part if—

(1) The qualification requirements are changed by Federal law; or

(2) The HMO shows good cause, consistent with the purposes of title XIII of the PHS Act.

(b) *Basis for finding of good cause.* (1) Grounds upon which CMS may find good cause include but are not limited to the following:

(i) The HMO has filed for reorganization under Federal bankruptcy provisions and the reorganization can only be approved with the waiver of the assurances.

(ii) State laws governing the entity have been changed after it signed the assurances so as to prohibit the HMO from being organized and operated in a manner consistent with the signed assurances.

(2) Changes in State laws do not constitute good cause to the extent that the changes are preempted by Federal law under section 1311 of the PHS Act.

(c) *Consequences of waiver.* If CMS waives any assurances regarding compliance with section 1301 of the PHS Act, CMS concurrently revokes the HMO's qualification unless the waiver is based on paragraph (a)(1) of this section.

[59 FR 49842, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

Subparts G–I [Reserved]

Subpart J—Qualifying Conditions for Medicare Contracts

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.400 Basis and scope.

(a) *Statutory basis.* The regulations in this subpart implement section 1876 of the Act, which authorizes Medicare payment to HMOs and CMPs that contract with CMS to furnish covered services to Medicare beneficiaries.

(b) *Scope.* (1) This subpart sets forth the requirements an HMO or CMP must meet in order to enter into a contract with CMS under section 1876 of the Act. It also specifies the procedures that CMS follows to evaluate applications and make determinations.

(2) The rules for payment to HMOs and CMPs are set forth in subparts N, O, and P of this part.

(3) The rules for HCPP participation in Medicare under section 1833(a)(1)(A) of the Act are set forth in subpart U of this part.

[60 FR 45675, Sept. 1, 1995]

§ 417.401 Definitions.

As used in this subpart and subparts K through R of this part, unless the context indicates otherwise—

Adjusted average per capita cost (AAPCC) means an actuarial estimate made by CMS in advance of an HMO's or CMP's contract period that represents what the average per capita cost to the Medicare program would be for each class of the HMO's or CMP's Medicare enrollees if they had received covered services other than through the HMO or CMP in the same geographic area or in a similar area.

Adjusted community rate (ACR) is the equivalent of the premium that a risk HMO or CMP would charge Medicare enrollees independently of Medicare payments if the HMO or CMP used the same rates it charges non-Medicare enrollees for a benefit package limited to covered Medicare services.

Arrangement means a written agreement between an HMO or CMP and another entity, under which—

(1) The other entity agrees to furnish specified services to the HMO's or CMP's Medicare enrollees;

(2) The HMO or CMP retains responsibility for the services; and

(3) Medicare payment to the HMO or CMP discharges the beneficiary's obligation to pay for the services.

Benefit stabilization fund means a fund established by CMS, at the request of a risk HMO or CMP, to withhold a portion of the per capita payments available to the HMO or CMP and pay that portion in a subsequent contract period for the purpose of stabilizing fluctuations in the availability of the additional benefits the HMO or CMP provides to its Medicare enrollees.

Cost contract means a Medicare contract under which CMS pays the HMO or CMP on a reasonable cost basis.

Cost HMO or CMP means an HMO or CMP that has in effect a cost contract

with CMS under section 1876 of the Act and subpart L of this part.

Demonstration project means a demonstration project under section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 (note)), relating to the provision of services for which payment is made under Medicare on a prospectively determined basis.

Emergency services means covered inpatient or outpatient services that are furnished by an appropriate source other than the HMO or CMP and that meet the following conditions:

(1) Are needed immediately because of an injury or sudden illness.

(2) Are such that the time required to reach the HMO's or CMP's providers or suppliers (or alternatives authorized by the HMO or CMP) would mean risk of permanent damage to the enrollee's health.

Once initiated, the services continue to be considered emergency services as long as transfer of the enrollee to the HMO's or CMP's source of health care or authorized alternative is precluded because of risk to the enrollee's health or because transfer would be unreasonable, given the distance and the nature of the medical condition.

Geographic area means the area found by CMS to be the area within which the HMO or CMP furnishes, or arranges for furnishing, the full range of services that it offers to its Medicare enrollees.

Medicare enrollee means a Medicare beneficiary who has been identified on CMS records as an enrollee of an HMO or CMP that has a contract with CMS under section 1876 of the Act and subpart L of this part.

New Medicare enrollee means a Medicare beneficiary who—

(1) Enrolls with an HMO or CMP after the date on which the HMO or CMP first enters into a risk contract under subpart L of this part; and

(2) Was not enrolled with the HMO or CMP at the time he or she became entitled to benefits under Part A or eligible to enroll in Part B of Medicare.

Risk contract means a Medicare contract under which CMS pays the HMO or CMP on a risk basis for Medicare covered services.

Risk HMO or CMP means an HMO or CMP that has in effect a risk contract with CMS under section 1876 of the Act and subpart L of this part.

Urgently needed services means covered services that are needed by an enrollee who is temporarily absent from the HMO's or CMP's geographic area and that—

(1) Are required in order to prevent serious deterioration of the enrollee's health as a result of unforeseen injury or illness; and

(2) Cannot be delayed until the enrollee returns to the HMO's or CMP's geographic area.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 51986, Oct. 17, 1991; 58 FR 38072, July 15, 1993; 60 FR 45675, Sept. 1, 1995]

§417.402 Effective date of initial regulations.

(a) The changes made to section 1876 of the Act by section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 became effective on February 1, 1985, the effective date of the initial implementing regulations.

(b) No new cost plan contracts are accepted by CMS. CMS will, however, accept and approve applications to modify cost plan contracts in order to expand service areas, provided they are submitted on or before September 1, 2006, and CMS determines that the organization continues to meet regulatory requirements and the requirements in its cost plan contract. Section 1876 cost plan contracts will not be extended or renewed beyond December 31, 2007, where conditions in paragraph (c) of this section are present.

(c) *Mandatory HMO or CMP and contract non-renewal or service area reduction.* CMS will non-renew all or a portion of an HMO's or CMP's contracted service area using procedures in §417.492(b) and §417.494(a) for any period beginning on or after January 1, 2008, where-

(1) There were two or more coordinated care plan-model MA regional plans in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section; or

(2) There were two or more coordinated care plan-model MA local plans

in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section.

(3) *Minimum enrollment requirements.* (i) With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to the Metropolitan Statistical Area, 5,000 enrolled individuals.

(ii) With respect to any service area or portion of a service area that is not within a Metropolitan Statistical Area described in paragraph (c)(3)(i) of this section, 1,500 individuals.

[63 FR 35066, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4713, Jan. 28, 2005]

§ 417.404 General requirements.

(a) In order to contract with CMS under the Medicare program, an entity must—

(1) Be determined by CMS to be an HMO or CMP (in accordance with §§ 117.142 and 417.407, respectively); and

(2) Comply with the contract requirements set forth in subpart L of this part.

(b) CMS enters into or renews a contract only if it determines that action would be consistent with the effective and efficient implementation of section 1876 of the Act.

[60 FR 45675, Sept. 1, 1995]

§ 417.406 Application and determination.

(a) *Responsibility for making determinations.* CMS is responsible for determining whether an entity meets the requirements to be an HMO or CMP.

(b) *Application requirements.* (1) The application requirements for HMOs are set forth in § 417.143.

(2) The requirements of § 417.143 also apply to CMPs except that there are no application fees.

(c) *Determination.* CMS uses the procedures set forth in § 417.144(a) through (d) to determine whether an entity is an HMO or CMP.

(d) *Oversight of continuing compliance.* (1) CMS oversees an entity's continued compliance with the requirements for an HMO as defined in § 417.1 or for a CMP as set forth in § 417.407.

(2) If an entity no longer meets those requirements, CMS terminates the contract of that entity in accordance with § 417.494.

[60 FR 45675, Sept. 1, 1995]

§ 417.407 Requirements for a Competitive Medical Plan (CMP).

(a) *General rule.* To qualify as a CMP, an entity must be organized under the laws of a State and must meet the requirements of paragraphs (b) through (f) of this section.

(b) *Required services.* (1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, the entity furnishes to its enrollees at least the following services:

(i) Physicians' services performed by physicians.

(ii) Laboratory, x-ray, emergency, and preventive services.

(iii) Out-of-area coverage.

(iv) Inpatient hospital services.

(2) Exception for Medicaid prepayment risk contracts. An entity that had, before 1970, a Medicaid prepayment risk contract that did not include provision of inpatient hospital services is not required to provide those services.

(c) *Compensation for services.* The entity receives compensation (except for deductibles, coinsurance, and copayments) for the health care services it provides to enrollees on a periodic, prepaid capitation basis regardless of the frequency, extent, or kind of services provided to any enrollee.

(d) *Source of physicians' services.* The entity provides physicians' services primarily through—

(1) Physicians who are employees or partners of the entity; or

(2) Physicians or groups of physicians (organized on a group or individual practice basis) under contract with the entity to provide physicians' services.

(e) *Assumption of financial risk.* The rules set forth in § 417.120(b) for HMOs apply also to CMPs except that reference to ''basic services'' must be read as reference to the required services listed in paragraph (b) of this section.

(f) *Protection of enrollees.* The entity provides adequately against the risk of

insolvency by meeting the requirements of §§417.120(a) and 417.122 for protection of enrollees against loss of benefits and liability for payment of any fees that are the legal responsibility of the entity.

[60 FR 45675, Sept. 1, 1995]

§417.408 Contract application process.

(a) *Contents of application.* (1) The application for a contract must include supporting information in the form and detail required by CMS. (2) Whenever feasible, CMS exempts the HMO or CMP from resubmittal of information it has already submitted to CMS in connection with a determination made under the provisions of §417.406.

(b) *Approval of application.* (1) If CMS approves the application, it gives written notice to the HMO or CMP, indicating that it meets the requirements for either a risk or reasonable cost contract or only for a reasonable cost contract.

(2) If the HMO or CMP is dissatisfied with a determination that it meets the requirements only for a reasonable cost contract, it may request reconsideration in accordance with the procedures specified in subpart R of this part.

(c) *Denial of application.* If CMS denies the application, it gives written notice to the HMO or CMP indicating—

(1) That it does not meet the contract requirements under section 1876 of the Act;

(2) The reasons why the HMO or CMP does not meet the contract requirements; and

(3) The HMO's or CMP's right to request reconsideration in accordance with the procedures specified in subpart R of this part.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§417.410 Qualifying conditions: General rules.

(a) *Basic requirement.* In order to qualify for a contract with CMS under this subpart, an HMO or CMP must demonstrate its ability to enroll Medicare beneficiaries and other individuals and groups and to deliver a specified comprehensive range of high quality services efficiently, effectively, and economically to its Medicare enrollees.

(b) *Other qualifying conditions.* An HMO or CMP must meet qualifying conditions that pertain to operating experience, enrollment, range of services, furnishing of services, and a quality assurance program.

(c) *Standards.* Generally, each qualifying condition is interpreted by a series of standards that are used in surveying an HMO or CMP to determine its qualifications for a Medicare contract.

(d) *Application of standards.* Application of the standards enables the surveyor to determine—

(1) The HMO's or CMP's activities;

(2) The extent to which the HMO or CMP complies with each condition;

(3) The nature and extent of any deficiencies; and

(4) The need for improvement if CMS should enter into a contract with the HMO or CMP.

(e) *Requirements for a risk contract.* An HMO or CMP may enter into a risk contract with CMS if it—

(1) Meets all the applicable requirements in the statute and regulations;

(2) Has at least 5,000 enrollees or 1,500 enrollees if it serves a primarily rural area as defined in §417.413(b)(3);

(3) Has at least 75 Medicare enrollees or has an acceptable plan to achieve this Medicare membership within 2 years;

(4) Satisfies CMS that it can bear the potential losses of a risk contract; and

(5) Has not previously terminated or failed to renew a risk contract within the preceding 5 years, unless CMS determines that circumstances warrant special consideration.

(f) *Requirements for a reasonable cost sontract.* An HMO or CMP may enter into a reasonable cost contract if it meets one of the following:

(1) The HMO or CMP qualifies for a risk contract, but chooses a reasonable cost contract.

(2) The HMO or CMP meets the conditions for entering into a risk contract specified in paragraph (e) of this section except that CMS does not judge the HMO or CMP capable of bearing the potential losses of a risk contract.

(g) Regulations on reasonable cost and risk reimbursement are set forth in subparts O and P of this part.

[50 FR 20570, May 17, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§ 417.412 Qualifying condition: Administration and management.

The HMO or CMP must demonstrate that it—

(a) Has sufficient administrative capability to carry out the requirements of the contract; and

(b) Does not have any agents or management staff or persons with ownership or control interests who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, or social service programs under title XX of the Act.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§ 417.413 Qualifying condition: Operating experience and enrollment.

(a) *Condition.* The HMO or CMP must demonstrate that it has operating experience and an enrolled population sufficient to provide a reasonable basis for establishing a prospective per capita reimbursement rate or a reasonable cost reimbursement rate, as appropriate.

(b) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a risk basis.* To be eligible to contract on a risk basis—

(1) A nonrural HMO or CMP must currently have the following:

(i) At least 5,000 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(2) A rural HMO or CMP must currently have—

(i) At least 1,500 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(3) For purposes of this paragraph, an HMO or CMP is considered rural if at least 50 percent of its enrollees reside in nonmetropolitan areas. A nonmetropolitan area is an area—

(i) No part of which is within a metropolitan statistical area (MSA) as designated by the Executive Office of Management and Budget; and

(ii) That does not contain a city whose population exceeds 50,000 individuals.

(4) A subdivision or subsidiary of an HMO or CMP that meets the requirements of paragraph (b)(1) or (b)(2) of this section need not demonstrate that it meets those requirements as an independent unit if the HMO or CMP assumes responsibility for the financial risk, and adequate management and supervision of health care services furnished by its subdivision or subsidiary.

(c) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a cost basis.* To be eligible to contract on a reasonable cost basis, an HMO or CMP must currently have enrollees sufficient in number to provide a reasonable basis for entering into a contract, as follows:

(1) At least 1,500 enrollees.

(2) At least 75 Medicare enrollees, or a plan acceptable to CMS for achieving—

(i) A Medicare enrollment of 75 within 2 years from the beginning of its initial contract period; and

(ii) At least 250 Medicare enrollees by the beginning of its fourth contract period.

(d) *Standard: Composition of enrollment*—(1) *Requirement.* Except as specified in paragraphs (d)(2) and (e) of this section, not more than 50 percent of an HMO's or CMP's enrollment may be Medicare beneficiaries.

(2) *Waiver of composition of enrollment standard.* CMS may waive compliance with the requirements of paragraph (d)(1) of this section if the HMO or CMP has made and is making reasonable efforts to enroll individuals who are not Medicare beneficiaries and it meets one of the following requirements:

(i) The HMO or CMP serves a geographic area in which Medicare beneficiaries and Medicaid recipients constitute more than 50 percent of the population. (CMS does not grant a waiver that would permit the percentage of Medicare and Medicaid enrollees to exceed the percentage of Medicare

beneficiaries and Medicaid recipients in the population of the geographic area.)

(ii) The HMO or CMP is owned and operated by a government entity. The waiver may be for a period up to three years after the date the HMO or CMP first enters into a contract under this subpart, and may not be extended.

(iii) The HMO or CMP requests waiver of the composition rule because it is in the public interest. The organization provides documentation that supports one of the following:

(A) The organization serves a medically underserved rural or urban area.

(B) The organization demonstrates a long-term business and community service commitment to the area.

(C) The organization believes that a waiver is necessary to promote managed care choices in an area with limited or no managed care choices.

(3) *Waiver granted on or before October 21, 1986.* An HMO or CMP (or a successor HMO or CMP) that as of October 21, 1986, had been granted an exception, waiver, or modification of the requirements of paragraph (d)(1) of this section, but that does not meet the requirements of paragraph (d)(2) of this section, must make (and throughout the period of the exception, waiver, or modification continue to make) reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by CMS.

(i) If CMS determines that the HMO or CMP has complied, or made significant progress toward compliance, with the approved schedule, and that an extension is in the best interest of the Medicare program, CMS may extend the waiver of modification.

(ii) If CMS determines that the HMO or CMP has not complied with the approved schedule, CMS may apply the sanctions described in paragraphs (d)(6) and (d)(7) of this section.

(4) *Basis for application of sanctions.* CMS may, as an alternative to contract termination, apply the sanctions specified in paragraph (d)(6) of this section if CMS determines that the HMO or CMP is not complying with the requirements in paragraphs (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(5) *Notice of sanction.* Before applying the sanctions specified in paragraph (d)(6) of this section, CMS sends a written notice to the HMO or CMP stating the proposed action and its basis. CMS gives the HMO or CMP 15 days after the date of the notice to provide evidence establishing the HMO's or CMP's compliance with the requirements in paragraph (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(6) *Sanctions.* If, following review of the HMO's or CMP's timely response to CMS's notice, CMS determines that an HMO or CMP does not comply with the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section, CMS may apply either of the following sanctions:

(i) Require the HMO or CMP to stop accepting new enrollment applications after a date specified by CMS.

(ii) Deny payment for individuals who are formally added or ''accreted'' to CMS's records as Medicare enrollees after a date specified by CMS.

(7) *Termination by CMS.* In addition to the sanctions described in paragraph (d)(6) of this section. CMS may decline to renew an HMO's or CMP's contract in accordance with §417.492(b), or terminate its contract in accordance with §417.494(b) if CMS determines that the HMO or CMP no longer substantially meets the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section.

(8) *Termination of composition standard.* The 50 percent composition of Medicare beneficiaries terminates for all managed care plans on December 31, 1998.

(e) *Standard: Open enrollment.* (1) Except as specified in paragraph (e)(2) of this section, an HMO or CMP must enroll Medicare beneficiaries on a first-come, first-served basis to the limit of its capacity and provide annual open enrollment periods of at least 30 days duration for Medicare beneficiaries.

(2) CMS may waive the requirement of paragraph (e)(1) of this section if compliance would prevent compliance with the limitation on enrollment of Medicare beneficiaries and Medicaid recipients (paragraph (d) of this section) or result in an enrollment substantially nonrepresentative of the population of the HMO's or CMP's geographic area. The enrollment would be

''substantially nonrepresentative'' if the proportion of a subgroup to the total enrollment exceeded, by 10 percent or more, its proportion of the population in the HMO's or CMP's geographic area, as shown by census data or other data acceptable to CMS. For purposes of this paragraph, a subgroup means a class of Medicare enrollees as defined in § 417.582.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995; 63 FR 35066, June 26, 1998]

§ 417.414 Qualifying condition: Range of services.

(a) *Condition*. The HMO or CMP must demonstrate that it is capable of delivering to Medicare enrollees the range of services required in accordance with this section.

(b) *Standard: Range of services furnished by eligible HMOs or CMPs*. (1) *Basic requirement*. Except as specified in paragraph (b)(3) of this section, an HMO or CMP must furnish to its Medicare enrollees (directly or through arrangements with others) all the Medicare services to which those enrollees are entitled to the extent that they are available to Medicare beneficiaries who reside in the HMO's or CMP's geographic area but are not enrolled in the HMO or CMP.

(2) *Criteria for availability*. The services are considered available if—

(i) The sources are located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to sources outside that geographic area.

(3) *Exception for hospice care*. An HMO or CMP is not required to furnish hospice care as described in part 418 of this chapter. However, HMOs or CMPs must inform their Medicare enrollees about the availability of hospice care if—

(i) A hospice participating in Medicare is located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to hospices outside the geographic area.

(c) *Standard: Financial responsibility for services furnished outside the HMO or CMP*. (1) An HMO or CMP must assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services (as defined in § 417.401) that are obtained by its Medicare enrollees from providers and suppliers outside the HMO or CMP even in the absence of the HMO's or CMP's prior approval.

(2) An HMO or CMP must assume financial responsibility for services that the Medicare enrollee attempted to obtain from the HMO or CMP, but that the HMO or CMP failed to furnish or unreasonably denied, and that are found, upon appeal by the enrollee under subpart Q of this part, to be services that the enrollee was entitled to have furnished to him or her by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.416 Qualifying condition: Furnishing of services.

(a) *Condition*. The HMO or CMP must furnish the required services to its Medicare enrollees through providers and suppliers that meet applicable Medicare statutory definitions and implementing regulations. The HMO or CMP must also ensure that the required services, additional services, and any other supplemental services for which the Medicare enrollee has contracted are available and accessible and are furnished in a manner that ensures continuity.

(b) *Standard: Conformance with conditions of participation, conditions for coverage, and conditions for certification*. (1) Hospitals, SNFs, HHAs, CORFs, and providers of outpatient physical therapy or speech-language pathology services must meet the applicable conditions of participation in Medicare, as set forth elsewhere in this chapter.

(2) Suppliers must meet the conditions for coverage or conditions for certification of their services, as set forth elsewhere in this chapter.

(3) If more than one type of practitioner is qualified to furnish a particular service, the HMO or CMP may select the type of practitioner to be used.

(c) *Standard: Physician supervision*. The HMO or CMP must provide for supervision by a physician of other health care professionals who are directly involved in the provision of

health care as generally authorized under section 1861 of the Act. Except as specified in paragraph (d) of this section, with respect to medical services furnished in an HMO's or CMP's clinic or the office of a physician with whom the HMO or CMP has a service agreement, the HMO or CMP must ensure that—

(1) Services furnished by paramedical, ancillary, and other nonphysician personnel are furnished under the direct supervision of a physician;

(2) A physician is present to perform medical (as opposed to administrative) services whenever the clinics or offices are open; and

(3) Each patient is under the care of a physician.

(d) *Exceptions to physician supervision requirement*. The following services may be furnished without the direct personal supervision of a physician:

(1) Services of physician assistants and nurse practitioners (as defined in §491.2 of this chapter), and the services and supplies incident to their services. The conditions for payment, as set forth in §§405.2414 and 405.2415 of this chapter for services furnished by rural health clinics and Federally qualified health centers, respectively, also apply when those services are furnished by an HMO or CMP.

(2) When furnished by an HMO or CMP, services of clinical psychologists who meet the qualifications specified in §410.71(d) of this chapter, and the services and supplies incident to their professional services.

(3) When an HMO or CMP contracts on—

(i) A risk basis, the services of a clinical social worker (as defined at §410.73 of this chapter) and the services and supplies incident to their professional services; or

(ii) A cost basis, the services of a clinical social worker (as defined in §410.73 of this chapter). Services incident to the professional services of a clinical social worker furnished by an HMO or CMP contracting on a cost basis are not covered by Medicare and payment will not be made for these services.

(e) *Standard: Accessibility and continuity*. (1) The HMO or CMP must ensure that the required services and any other services for which Medicare enrollees have contracted are accessible, with reasonable promptness, to the enrollees with respect to geographic location, hours of operation, and provision of after hours service. Medically necessary emergency services must be available twenty-four hours a day, seven days a week.

(2) The HMO or CMP must maintain a health (including medical) recordkeeping system through which pertinent information relating to the health care of its Medicare enrollees is accumulated and is readily available to appropriate professionals.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 63 FR 20130, Apr. 23, 1998]

§417.418 Qualifying condition: Quality assurance program.

(a) *Condition*. The HMO or CMP must make arrangements for a quality assurance program that meets the requirements of this section.

(b) *Standard*. An HMO or CMP must have an ongoing quality assurance program that meets the requirements set forth in §417.106(a).

[58 FR 38072, July 15, 1993]

Subpart K—Enrollment, Entitlement, and Disenrollment under Medicare Contract

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§417.420 Basic rules on enrollment and entitlement.

(a) *Enrollment*. Individuals who are entitled to benefits under both Part A and Part B of Medicare or only Part B may elect to receive those benefits through an HMO or CMP that has in effect a contract with CMS under subpart L of this part.

(b) *Entitlement*. If a Medicare beneficiary enrolls with an HMO or CMP, CMS pays the HMO or CMP on his or her behalf for the services to which he or she is entitled.

(c) *Beneficiary liability*. (1) The HMO or CMP may require payment, in the form of premiums or otherwise, from individuals for services not covered under Medicare, as well as deductible

and coinsurance amounts attributable to Medicare covered services.

(2) As described in § 417.448, Medicare enrollees of risk HMOs or CMPs are liable for services that they obtain from sources other than the HMO or CMP, unless the services are—

(i) Emergency or urgently needed; or

(ii) Determined, on appeal under subpart Q of this part, to be services that should have been furnished by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.422 Eligibility to enroll in an HMO or CMP.

Except as specified in §§ 417.423 and 417.424, an HMO or CMP must enroll, either for an indefinite period or for a specified period of at least 12 months, any individual who—

(a) Is entitled to Medicare benefits under Parts A and B or under Part B only;

(b) Lives within the geographic area served by the HMO or CMP;

(c) Is not enrolled in any other HMO or CMP that has entered into a contract under subpart L of this part;

(d) During an enrollment period of the HMO or CMP, completes and signs the HMO's or CMP's application form and gives whatever information is required for enrollment;

(e) Agrees to abide by the HMO's or CMP's rules after they are disclosed to him or her in connection with the enrollment process;

(f) Is not denied enrollment by the HMO or CMP under a selection policy, if any, that has been approved by CMS under § 417.424(b); and

(g) Is not denied enrollment by the HMO or CMP on the basis of any of the administrative criteria concerning denial of enrollment in § 417.424(a).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.423 Special rules: ESRD and hospice patients.

(a) *ESRD patients.* (1) A Medicare beneficiary who has been medically determined to have end-stage renal disease is not eligible to enroll in an HMO or CMP.

(2) However, if a beneficiary is already enrolled in an HMO or CMP when he or she is determined to have end-stage renal disease, the HMO or CMP—

(i) Must reenroll the beneficiary as required by § 417.434; and

(ii) May not disenroll the beneficiary except as provided in § 417.460.

(b) *Hospice patients.* A Medicare beneficiary who elects hospice care under § 418.24 of this chapter is not eligible to enroll in an HMO or CMP as long as the hospice election remains in effect.

[60 FR 45677, Sept. 1, 1995]

§ 417.424 Denial of enrollment.

(a) *Basis for denial.* An HMO or CMP may deny enrollment to an individual who meets the criteria of § 417.422 if acceptance would—

(1) Cause the number of enrollees who are Medicare or Medicaid beneficiaries to exceed 50 percent of the HMO's or CMP's total enrollment;

(2) Prevent the HMO or CMP from complying with any of the other contract qualifying conditions set forth in subpart J of this part;

(3) Require the HMO or CMP to exceed its enrollment capacity; or

(4) Cause the enrollment to become substantially nonrepresentative of the general population in the HMO's or CMP's geographic area.

(b) *Selection policies.* (1) Denial under paragraph (a)(4) of this section must be in accordance with written selection policies approved by CMS. (2) Enrollment of individuals will not be considered to make the enrollment of the HMO or CMP substantially nonrepresentative of the general population in the HMO's or CMP's geographic area unless, as a result of the enrollment, the proportion of the subgroup of enrollees to which the enrollee belongs as compared to the HMO's or CMP's total enrollment exceeds by at least ten percent the subgroup's proportion of the general population in the geographic area of the HMO or CMP. (A subgroup is a class of Medicare enrollees of an HMO or CMP that CMS constructs on the basis of actuarial factors.)

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§417.426 Open enrollment requirements.

(a) *Basic requirements.* (1) HMOs or CMPs must provide open enrollment for Medicare beneficiaries for at least 30 consecutive days during each contract year.

(2) During open enrollment, the HMO or CMP must enroll eligible Medicare beneficiaries in the order in which their applications are received and until its enrollment capacity is reached.

(3) The HMO or CMP may accept applications from Medicare beneficiaries after it has reached capacity if it places those individuals on a waiting list and enrolls them in chronological order as vacancies occur.

(4) An HMO or CMP with a risk contract must accept applications from eligible Medicare beneficiaries during the month of November 1998.

(b) *Capacity to accept new enrollees.* (1) If an HMO or CMP chooses to limit enrollments because of its capacity, it must notify CMS at least 90 days before the beginning of its open enrollment period and, at that time, provide CMS with its reasons for limiting enrollment.

(2) CMS evaluates the HMO's or CMP's submittal under paragraph (b)(1) of this section.

(3) The HMO or CMP must promptly notify CMS if there is any change in its enrollment capacity.

(c) *Reserved vacancies.* (1) Subject to CMS's approval, an HMO or CMP may set aside a reasonable number of vacancies for an anticipated new group contract or for anticipated new enrollees under an existing group contract that will have its enrollment period after the Medicare open enrollment period during the contract year.

(2) Any set aside vacancies that are not filled within a reasonable time after the beginning of the group contract enrollment period must be made available to Medicare beneficiaries and other nongroup applicants under the requirements of this subpart.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 63 FR 35066, June 26, 1998]

§417.428 Marketing activities.

(a) *Required marketing activities.* An HMO or CMP must meet the following requirements:

(1) Offer its plan to Medicare beneficiaries and provide to those interested in enrolling, adequate written descriptions of the HMO's or CMP's rules, procedures, benefits, fees and other charges, services, and other information necessary for beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period (whether time limited or continuous) in an appropriate manner through appropriate media, throughout its enrollment area.

(3) Submit all marketing materials to CMS at least 45 days before their planned distribution.

(4) Include in the HMO's or CMP's written materials provided to prospective enrollees prior to enrollment, notice that the HMO or CMP is authorized by law to terminate or refuse to renew its contract with CMS, that CMS may also choose to terminate or refuse to renew its contact with the HMO or CMP and that termination or nonrenewal may result in termination of the individual's enrollment in the HMO or CMP.

(b) *Prohibited marketing activities—general.* In offering its plan to Medicare beneficiaries, an HMO or CMP may not engage in any of the following practices or activities:

(1) Practices that are discriminatory. For example, the HMO or CMP may not engage in any activity intended to recruit Medicare beneficiaries from higher income areas (usually an indicator of better health) without making a comparable effort to enroll Medicare beneficiaries from lower income areas.

(2) Activities that could mislead or confuse Medicare beneficiaries, or misrepresent the HMO or CMP its marketing representatives, or CMS. For example, the HMO or CMP may not claim that it is recommended or endorsed by CMS or that CMS recommends that the beneficiary enroll in the HMO or CMP. It may, however, explain that the entity is approved as an HMO or CMP for purposes of participation in Medicare.

(3) Offers of gifts or payment as an inducement to enroll in the HMO or

CMP. This does not prohibit the explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the HMO or CMP such as eligibility to enroll in a supplemental benefit plan that covers deductibles and coinsurance or preventive services.

(4) Door-to-door solicitation of Medicare beneficiaries.

(5) Distribution of marketing materials if, before the expiration of the 45-day period described in paragraph (a)(3) of this section, the HMO or CMP receives written notice from CMS that CMS has disapproved the material because it is inaccurate or misleading or it misrepresents the HMO or CMP, its marketing representatives or CMS.

(c) *Marketing activities of risk HMOs or CMPs* In addition to the generally permitted or prohibited marketing activities described in paragraphs (a) and (b) of this section, a risk HMO or CMP must provide potential Medicare enrollees with adequate written descriptions of the additional benefits or services, or reductions in premiums, deductible or copayments that may pertain under payment on a risk basis.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.430 Application procedures.

(a) *Application forms.* (1) The application form must comply with CMS instructions regarding format and content and must include the beneficiary's signature and authorization for disclosure and exchange of necessary information between CMS and the HMO or CMP.

(2) The HMO or CMP must file and retain application forms for the period specified in CMS instructions.

(b) *Handling of applications.* An HMO or CMP must have an effective system for receiving, controlling, and processing applications from Medicare beneficiaries. The system must meet the following conditions and requirements:

(1) Each application is dated as of the day it is received.

(2) Applications are processed in chronological order by date of receipt.

(3) The HMO or CMP gives the beneficiary prompt written notice of acceptance or rejection of the application.

(4) The notice of acceptance—

(i) Specifies the date on which the HMO or CMP will request CMS to make the enrollment effective; or

(ii) If the HMO or CMP is currently enrolled to capacity, explains the procedures that will be followed when vacancies occur.

(5) The notice of denial explains the reason for denial.

(6) The HMO or CMP transmits the information necessary for CMS to add the beneficiary to its records of the HMO's or CMP's Medicare enrollees—

(i) Within 30 days from the date of application or from the date a vacancy occurs for an applicant who was accepted (for future enrollment) while there were no vacancies; or

(ii) Within an additional period of time approved by CMS on a showing by the HMO or CMP that it needs more time.

(7) The HMO or CMP promptly notifies the beneficiary of the effective month of his or her enrollment as a Medicare enrollee, when it receives that information from CMS.

(8) If the HMO or CMP accepts applications while it is enrolled to capacity, its procedures ensure that vacancies are filled in chronological order by date of application of beneficiaries who are still eligible to enroll, unless that would result in failure to comply with any of the qualifying conditions set forth in § 417.413.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.432 Conversion of enrollment.

(a) *Basic rule.* An HMO or CMP must accept as a Medicare enrollee any individual who is enrolled in the HMO or CMP for the month immediately before the month in which he or she is entitled to both Medicare Parts A and B or Part B only.

(b) *Effective date of conversion.* Unless the individual chooses to disenroll from the HMO or CMP the individual's conversion to a Medicare enrollee is effective the month in which he or she is entitled to both Medicare Parts A and B or Part B only.

(c) *Prohibition against disenrollment.* An HMO or CMP may not disenroll an individual who is converting under the provisions of paragraph (a) of this section unless one of the conditions specified in §417.460 is met.

(d) *Application form.* The individual who is converting must sign an application form as described in §417.430(a).

(e) *Expedited submittal of information to CMS.* The HMO or CMP must notify CMS, within the following time frames, of the enrollee's authorization for disclosure and exchange of information and the information necessary for CMS to include the enrollee in its records as a Medicare enrollee of the HMO or CMP:

(1) At least 30, but no earlier than 90, days before the enrollee—

(i) Attains age 65; or

(ii) Reaches his or her 25th month of entitlement to social security disability benefits under title II of the Act or railroad retirement disability benefits under section 7(d) of the Railroad Retirement Act of 1974.

(2) Within 30 days after the enrollee initiates a course of renal dialysis, or on or before the day he or she enters a hospital in anticipation of a kidney transplant.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§417.434 Reenrollment.

If an HMO or CMP requires periodic reenrollment, it must reenroll Medicare enrollees unless there is a basis for disenrollment as set forth in §417.460.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.436 Rules for enrollees.

(a) *Maintaining rules.* An HMO or CMP must maintain written rules that deal with, but need not be limited to the following:

(1) All benefits provided under the contract, as described in §417.440.

(2) How and where to obtain services from or through the HMO or CMP.

(3) The restrictions on coverage for services furnished from sources outside a risk HMO or CMP, other than emergency services and urgently needed services (as defined in §417.401).

(4) The obligation of the HMO or CMP to assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services as required by §417.414(c).

(5) Any services other than the emergency or urgently needed services that the HMO or CMP chooses to provide as permitted by this part, from sources outside the HMO or CMP. A cost HMO or CMP must disclose that the enrollee may receive services through any Medicare providers and suppliers.

(6) Premium information, including the amount (or if the amount cannot be included, the telephone number of the source from which this information may be obtained) and the procedures for paying premiums and other charges for which enrollees may be liable.

(7) Grievance and appeal procedures.

(8) Disenrollment rights.

(9) The obligation of an enrollee who is leaving the HMO's or CMP's geographic area for more than 90 days to notify the HMO or CMP of the move or extended absence and the HMO's or CMP's policies concerning retention of enrollees who leave the geographic area for more than 90 days, as described in §417.460(a)(2).

(10) The expiration date of the Medicare contract with CMS and notice that both CMS and the HMO or CMP are authorized by law to terminate or refuse to renew the contract, and that termination or nonrenewal of the contract may result in termination of the individual's enrollment in the HMO or CMP.

(11) Advance directives as specified in paragraph (d) of this section.

(12) Any other matters that CMS may prescribe.

(b) *Availability of rules.* The HMO or CMP must furnish a copy of the rules to each Medicare enrollee at the time of enrollment and at least annually thereafter.

(c) *Changes in rules.* If an HMO or CMP changes its rules, it must submit the changes to CMS in accordance with §417.428(a)(3), and notify its Medicare enrollees of the changes at least 30 days before the effective date of the changes.

(d) *Advance directives.* (1) An HMO or CMP must maintain written policies

and procedures concerning advance directives, as defined in § 489.100 of this chapter, with respect to all adult individuals receiving medical care by or through the HMO or CMP and are required to:

(i) Provide written information to those individuals concerning—

(A) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Such information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law; and

(B) The HMO's or CMP's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the HMO or CMP cannot implement an advance directive as a matter of conscience. At a minimum, this statement should:

(*1*) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(*2*) Identify the state legal authority permitting such objection; and

(*3*) Describe the range of medical conditions or procedures affected by the conscience objection.

(ii) Provide the information specified in paragraphs (d)(1)(i) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the HMO or CMP may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The HMO or CMP is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(iii) Document in the individual's medical record whether or not the individual has executed an advance directive;

(iv) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(v) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives;

(vi) Provide for education of staff concerning its policies and procedures on advance directives; and

(vii) Provide for community education regarding advance directives that may include material required in paragraph (d)(1)(i)(A) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the HMO or CMP. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An HMO or CMP must be able to document its community education efforts.

(2) The HMO or CMP—(i) Is not required to provide care that conflicts with an advance directive.

(ii) Is not required to implement an advance directive if, as a matter of conscience, the HMO or CMP cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(3) The HMO or CMP must inform individuals that complaints concerning non-compliance with the advance directive requirements may be filed with

the State survey and certification agency.

[58 FR 38072, July 15, 1993, as amended at 59 FR 49843, Sept. 30, 1994; 60 FR 33292, June 27, 1995]

§ 417.440 Entitlement to health care services from an HMO or CMP.

(a) *Basic rules*. (1) Subject to the conditions and limitations set forth in this subpart, a Medicare enrollee of an HMO or CMP is entitled to receive health care services and supplies directly from, or through arrangements made by, the HMO or CMP as specified in this section and §§ 417.442–417.446.

(2) A Medicare enrollee is also entitled to receive timely and reasonable payment directly (or have payment made on his or her behalf) for services he or she obtained from a provider or supplier outside the HMO or CMP if those services are—

(i) Emergency services or urgently needed services as defined § 417.401;

(ii) Services denied by the HMO or CMP and found (upon appeal under subpart Q of this part) to be services the enrollee was entitled to have furnished by the HMO or CMP.

(b) *Scope of services*. (1) *Part A and Part B services*. Except as specified in paragraphs (c), (d), and (e) of this section, a Medicare enrollee is entitled to receive from an HMO or CMP all the Medicare-covered services that are available to individuals residing in the HMO's or CMP's geographic area, as follows:

(i) Medicare Part A and Part B services if the enrollee is entitled to benefits under both programs.

(ii) Medicare Part B services if the enrollee is entitled only under that program.

(2) *Supplemental services elected by an enrollee*. (i) Except as provided under paragraph (b)(2)(ii) of this section, a Medicare enrollee of an HMO or CMP may elect to pay for optional services that are offered by the HMO or CMP in addition to the covered Part A and Part B services.

(ii) An HMO or CMP may elect to provide qualified prescription drug coverage (as defined at § 423.104 of this chapter) as an optional supplemental service in accordance with the applicable requirements under part 423 of this chapter, including § 423.104(f)(4) of this chapter.

(iii) The HMO or CMP may not set health status standards for those enrollees whom it accepts for these optional supplemental services.

(3) *Supplemental services imposed by a risk HMO or CMP*. (i) Subject to CMS's approval, a risk HMO or CMP may require Medicare enrollees to accept and pay for services in addition to those covered by Medicare. (ii) If the HMO or CMP elects this option, it must impose the requirement on all Medicare enrollees, without regard to health status. (iii) CMS approves supplemental benefits of this type if CMS determines that imposition of the requirements will not discourage other Medicare beneficiaries from enrolling in the risk HMO or CMP.

(4) *Additional benefits from risk HMOs or CMPs required by statute*. Subject to the conditions stated in § 417.442, a new Medicare enrollee or a current nonrisk Medicare enrollee who converts to risk reimbursement under § 417.444 is eligible to receive, in addition to the covered Part A and Part B benefits for which he or she is eligible, benefits consisting of one or both of the following:

(i) A reduction in the HMO's or CMP's premium rate or in other charges for services furnished to Medicare enrollees.

(ii) Provision of health benefits or services beyond the required Part A and Part B coverage.

(5) *Special supplemental benefits*. Under conditions described in § 417.444(c), current nonrisk Medicare enrollees who are not converted to the risk portion of the contract, may enroll in a special supplemental plan, if offered by the HMO or CMP, for some or all of the additional benefits described in paragraph (b)(4) of this section.

(c) *Limitation on hospice care*. (1) *Extent of limitation*. (i) *Basic rule*. Except as provided in paragraph (c)(1)(ii) of this section, a Medicare enrollee who elects to receive hospice care under § 418.24 of this chapter waives the right to receive from the HMO or CMP any Medicare services (including services equivalent to hospice care) that are related to the terminal condition for

which the enrollee elected hospice care, or to a related condition.

(ii) *Exception*. An enrollee who elects hospice care retains the right to services furnished by his or her attending physician if that physician—

(A) Is an employee or contractor of the HMO or CMP; and

(B) Is not an employee of the designated hospice and does not receive compensation from the hospice for those services.

(2) *Effective date of limitation*. The limitation in paragraph (c)(1) of this section begins on the effective date of the beneficiary's election of hospice care and remains in effect until the earlier of the following:

(i) The effective date of the enrollee's revocation of the election of hospice care as described in § 418.28 of this chapter.

(ii) The date the enrollee exhausts his or her hospice benefits.

(3) *Payment to HMO or CMP*. For the period that the Medicare enrollee's election of hospice care is in effect, CMS pays a cost HMO or CMP only as described in § 417.585.

(d) *Limitation on provision of inpatient hospital services*. If a beneficiary's effective date of coverage, as specified in § 417.450, in a risk HMO or CMP occurs during an inpatient stay in a hospital paid for under part 412 of this chapter, the HMO or CMP—

(1) Is not responsible for the provision of any of the inpatient hospital services under Part A during the stay and is not required to pay for those services;

(2) Must assume responsibility for payment for or provision of inpatient hospital services under Part A on the day after the day of discharge from the inpatient stay; and

(3) Is responsible for the full scope of services under paragraph (b) of this section, other than inpatient hospital services under Part A, beginning on the effective date of enrollment.

(e) *Extension of provision of inpatient hospital services*. If an enrollee's effective date of disenrollment, as defined by § 417.460, occurs during an inpatient stay in a hospital paid for under part 412 of this chapter and the stay is provided or arranged for by the HMO or CMP, or the HMO or CMP is financially responsible for the hospitalization under paragraph (a)(2) of this section, the HMO or CMP—

(1) Is financially responsible for payment of the inpatient services under Part A through the date the beneficiary is discharged from the inpatient stay; and

(2) Is not responsible for the provision of services, furnished on or after the effective date of disenrollment, other than inpatient hospital services under Part A.

(f) *Notice of noncoverage of inpatient hospital care*. (1) If an enrollee is an inpatient of a hospital, entitlement to inpatient hospital care continues until he or she receives notice of noncoverage of that care.

(2) Before giving notice of noncoverage, the HMO or CMP must obtain the concurrence of its affiliated physician responsible for the hospital care of the enrollee, or other physician as authorized by the HMO or CMP.

(3) The HMO or CMP must give the enrollee written notice that includes the following:

(i) The reason why inpatient hospital care is no longer needed.

(ii) The effective date of the enrollee's liability for continued inpatient care.

(iii) The enrollee's appeal rights.

(4) If the HMO or CMP delegates to the hospital the determination of noncoverage of inpatient care, the hospital obtains the concurrence of the HMO- or CMP-affiliated physician responsible for the hospital care of the enrollee, or other physician as authorized by the HMO or CMP, and sends notice, following the procedures set forth in § 412.42(c)(3) of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38079, July 15, 1993; 59 FR 59941, Nov. 21, 1994; 60 FR 45678, Sept. 1, 1995; 70 FR 4525, Jan. 28, 2005]

§ 417.442 Risk HMO's and CMP's: Conditions for provision of additional benefits.

(a) *General rule*. Except as provided in paragraph (b) of this section, a risk HMO or CMP must, during any contract period, provide to its Medicare

enrollees the additional benefits described in §417.440(b)(4) if its ACRs (calculated in accordance with §417.594) are less than the average per capita rates that CMS pays for the Medicare enrollees during the contract period.

(b) *Exceptions.* (1) *Reduced payment election.* An HMO or CMP is not obligated to furnish additional services under paragraph (a) of this section if it has requested a reduction in its monthly payment from CMS under §417.592(e), and it—

(i) Elects to receive reduced payment so that there is no difference between the average of its per capita rates of payment and its ACR; or

(ii) Elects to receive partially reduced payment and furnish Medicare enrollees with additional benefits described in §417.440 (b)(4) so that the combined value of benefits and reduced payment is equivalent to the difference between the average of its per capita rates of payment and its ACR.

(2) *Benefit stabilization fund.* An HMO or CMP may elect to have a part of the value of the additional benefits it must provide under paragraph (a) of this section withheld in a benefit stabilization fund as described in §417.596.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985; 58 FR 38082, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§417.444 Special rules for certain enrollees of risk HMOs and CMPs.

(a) *Applicability.* This section applies to any Medicare enrollee of a risk HMO or CMP who meets the following conditions:

(1) On February 1, 1985, was enrolled—

(i) In an HMO or CMP that had in effect a cost contract entered into under section 1876 of the Act in accordance with regulations in effect before February 1, 1985; or

(ii) In an HCPP that was being reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act.

(2) Has continued enrollment in the same entity without interruption or disenrolled after February 1, 1985, and later reenrolled in the same entity.

(b) *Retention of nonrisk status*—(1) A ''nonrisk'' enrollee is a Medicare beneficiary who meets the conditions of paragraph (a) of this section and is enrolled in an entity that enters into a risk contract as an HMO or CMP. A ''nonrisk'' enrollee may retain nonrisk status indefinitely unless CMS determines under paragraph (c)(1) of this section, that the enrollee's status must be changed, or the enrollee requests the change, as provided in paragraph (c)(2) of this section.

(2) A nonrisk enrollee of a risk HMO or CMP is not entitled to additional benefits under §417.442.

(c) *Conversion to risk status*—(1) *Conversion based on CMS determination.* If CMS determines that, for administrative reasons or because there are fewer than 75 current nonrisk Medicare enrollees remaining in the HMO or CMP, all of its nonrisk Medicare enrollees must be covered under the risk provisions of the contract, the conversion process is as follows:

(i) CMS notifies each affected enrollee of the decision at least 90 days prior to the effective date.

(ii) The nonrisk Medicare enrollees complete and sign forms stating that they understand and accept the new rules and benefits that will be applicable to them.

(iii) The HMO or CMP notifies each affected enrollee, in writing, at least 30 days in advance, of the date upon which his or her coverage under the risk portion of the contract takes effect.

(2) *Conversion based on enrollee's request.* A nonrisk Medicare enrollee requests, using a form identical or similar to the form described in paragraph (c)(1) of this section, that he or she be covered under the risk portion of the contract.

(d) *Notification.* An HMO or CMP converting from a cost contract to a risk contract must, within 60 days of signing the risk contract, inform nonrisk enrollees of their right to remain nonrisk Medicare enrollees or to convert to risk enrollment at any time in accordance with paragraph (c)(2) of this section.

[58 FR 38073, July 15, 1993]

§ 417.446 [Reserved]

§ 417.448 Restriction on payments for services received by Medicare enrollees of risk HMOs or CMPs.

(a) *Basic rule.* Except for emergency and urgently needed services as defined in § 417.401, risk HMOs or CMPs are not required to make payments to or on behalf of certain Medicare enrollees, for any services received by the enrollees that are not provided—

(1) Directly by the HMO or CMP; or

(2) Through arrangements made by the HMO or CMP.

(b) *Application.* The restriction on payments for services imposed by paragraph (a) of this section applies to services received by—

(1) New Medicare enrollees;

(2) Nonrisk Medicare enrollees who convert to risk reimbursement; and

(3) Nonrisk Medicare enrollees who elect special supplemental benefit plans.

(c) *End of restriction.* The restriction of payments imposed by paragraph (a) of this section ends when a Medicare enrollee leaves the HMO's or CMP's geographic area for an extended period as defined in § 471.460(a)(2) and the HMO or CMP and the enrollee make arrangements for enrollment to continue as provided in § 417.460(a)(2)(iv).

(d) *Timing.* The effective date for the end of the restriction on payments, as discussed in paragraph (c) of this section is the first day of the first month following the month in which the enrollee notifies the HMO or CMP as required in § 417.436(a)(9), that he or she has left the HMO's or CMP's geographic area for an extended period.

[51 FR 28573, Aug. 8, 1986, as amended at 56 FR 46571, Sept. 13, 1991; 58 FR 38079, July 15, 1993]

§ 417.450 Effective date of coverage.

(a) *Basic rules.* Except as specified in paragraph (b) of this section, and notwithstanding the provisions of § 417.440(d).

(1) CMS's liability for payments to an HMO or CMP on behalf of a Medicare beneficiary begins on the first day of the month in which he or she is—

(i) Entitled to Medicare benefits; and

(ii) Enrolled in an HMO or CMP; and

(2) The effective month of coverage may not be earlier than the first month after, nor later than the third month after the month in which CMS receives the information necessary to include the beneficiary as a Medicare enrollee of the HMO or CMP in CMS records.

(b) *Exceptions.* (1) CMS may approve a later month if it is requested by the HMO or CMP and the beneficiary.

(2) If an individual becomes an HMO or CMP enrollee before becoming entitled to Medicare Part B benefits, the effective month of coverage is the first month for which he or she becomes entitled to Medicare Part B benefits.

(c) *Notice of effective date of coverage.* For each beneficiary added to CMS's records as an enrollee of an HMO or CMP, CMS gives the HMO or CMP prompt written notice of the month with which CMS's liability begins.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§ 417.452 Liability of Medicare enrollees.

(a) *Deductibles and coinsurance.* (1) A Medicare enrollee of an HMO or CMP is responsible for applicable Medicare deductible and coinsurance amounts, unless the HMO's or CMP's charges for these amounts are reduced under the additional benefits provision of § 417.442.

(2) The deductible and coinsurance amounts may be paid by or on behalf of the enrollee in the form of a premium, membership fee, charge per unit, or other similar charge.

(3) The sum of the amounts the HMO or CMP charges its Medicare enrollees for Medicare deductibles and coinsurance may not exceed, on the average, the actuarial value of the deductible and coinsurance the Medicare enrollees otherwise would have been liable for had they not enrolled in the HMO or CMP or in another HMO or CMP.

(b) *Services not covered under Medicare.* Unless the services are provided as additional benefits under § 417.442, a Medicare enrollee of an HMO or CMP is liable for payment for—

(1) All services that are not covered under Medicare Part A or Part B; or

(2) If entitled only to Medicare Part B benefits, all services that are not covered under Medicare Part B.

(c) *Services for which Medicare is not primary payer.* A Medicare enrollee of an HMO or CMP is liable for payments made to the enrollee for all covered services for which Medicare is not the primary payer as provided in §417.528.

(d) *Optional supplemental benefits plan.* (1) The HMO or CMP may offer its Medicare enrollees a supplemental benefit plan to cover deductible and coinsurance amounts, or services not covered under Medicare, or both.

(2) If a supplemental benefit plan premium includes charges for both noncovered services and the deductible and coinsurance amounts applicable to covered services, the portion of the premium that is for deductibles and coinsurance must be computed separately and must be disclosed to the beneficiary during the enrollment process and before he or she elects coverage options.

(3) The sum of the amounts an HMO or CMP charges its Medicare enrollees for services that are not covered under Part A or Part B may not exceed the ACR for these services.

(e) *Coverage of Part A services for Part B-only Medicare enrollees.* If an HMO or CMP furnishes coverage of Medicare Part A services to a Medicare enrollee entitled to Part B only, the HMO's or CMP's premium (or other payment method) for these services may not exceed the ACR for these services. In addition, if a risk HMO or CMP furnishes these services and supplemental services, which are the same as the additional benefits furnished Medicare enrollees of the HMO or CMP who are entitled to benefits under both Parts A and B, the HMO's or CMP's combined premium for both these groups of services that the Part B enrollee must pay may not exceed 95 percent of the weighted average AAPCC for Part A services (or the Medicare payment for Part A services, if it is less) for the Medicare enrollee of the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§417.454 Charges to Medicare enrollees.

(a) *Limits on charges.* The HMO or CMP must agree to charge its Medicare enrollees only for the—

(1) Deductible and coinsurance amounts applicable to furnished covered services;

(2) Charges for noncovered services or services for which the enrollee is liable as described in §417.452; and

(3) Services for which Medicare is not the primary payor as provided in §417.528.

(b) *Limit on charges for inpatient hospital care.* If a Medicare enrollee who is an inpatient of a hospital requests immediate QIO review (as provided in §417.605) of any determination by the hospital furnishing services or the HMO or CMP that the inpatient hospital services will no longer be covered, the HMO or CMP may not charge the enrollee for any inpatient care costs incured before noon of the first working day after the QIO issues its review decision.

(c) *Reporting requirements.* A risk HMO or CMP must report, within 90 days after the end of the contract period, all premiums, enrollment fees, and other charges collected from its Medicare enrollees during that period.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 59 FR 59941, Nov. 21, 1994; 60 FR 45678, Sept. 1, 1995]

§417.456 Refunds to Medicare enrollees.

(a) *Definitions.* As used in this section—

Amounts incorrectly collected means amounts collected that are in excess of those specified in §417.452. It includes amounts collected when the enrollee was believed not entitled to Medicare benefits if the enrollee is later determined to have been entitled to Medicare benefits and CMS is liable for payments as specified in §417.450.

Other amounts due means amounts due a Medicare enrollee for services obtained outside the HMO or CMP if they were—

(1) Emergency services;

(2) Urgently needed services for which the HMO or CMP has assumed financial responsibility; or

(3) On appeal under subpart Q of this part, found to be services the enrollee was entitled to have furnished by the HMO or CMP.

(b) *Basic commitment.* An HMO or CMP must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and any other amounts due the enrollees or others on their behalf.

(c) *Refund by lump sum payment.* An HMO or CMP must make refunds to its current and former Medicare enrollees, or to others who have made payments on behalf of enrollees, by lump sum payment for the following:

(1) Incorrectly collected amounts that were not collected as premiums.

(2) Other amounts due.

(3) All amounts due, if the HMO or CMP is going out of business.

(d) *Refund by premium adjustment or lump sum payment or both.* An HMO or CMP may make refund by adjustment of future premiums, by lump sum payment, or by a combination of both methods, for amounts that were incorrectly collected in the form of premiums or through a combination of premium payments and other charges.

(e) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort by the HMO or CMP, the HMO or CMP must make the refund in accordance with State law.

(f) *Reduction by CMS.* If the HMO or CMP does not make refund in accordance with paragraphs (b) through (d) of this section by the end of the contract period following the contract period during which an amount was determined to be due an enrollee, CMS reduces its payment to the HMO or CMP by the amounts incorrectly collected or otherwise due, and arranges for those amounts to be paid to the Medicare enrollee.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§ 417.458 Recoupment of uncollected deductible and coinsurance amounts.

An HMO or CMP agrees not to recoup deductible and coinsurance amounts for which Medicare enrollees were liable in a previous contract period except in the following circumstances:

(a) The HMO or CMP failed to collect the deductible and coinsurance amounts during the contract period in which they were due because of—

(1) Underestimation of the actuarial value of the deductible and coinsurance amounts; or

(2) A billing error.

(b) The HMO or CMP has identified the amounts and obtained advance CMS approval of the recoupment and the method and timing of recoupment.

(c) The HMO or CMP collects these amounts no later than the end of the contract period following the contract period during which they were found to be due.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45678, Sept. 1, 1995]

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

(a) *General rule.* Except as provided in paragraphs (b) through (i) of this section, an HMO or CMP may not—

(1) Disenroll a Medicare beneficiary; or

(2) Orally or in writing, or by any action or inaction, request or encourage a Medicare enrollee to disenroll.

(b) *Bases for disenrollment: Overview.* (1) *Optional disenrollment.* Generally, an HMO or CMP may disenroll a Medicare enrollee if he or she—

(i) Fails to pay the required premiums or other charges;

(ii) Commits fraud or permits abuse of his or her enrollment card; or

(iii) Behaves in a manner that seriously impairs the HMO's or CMP's ability to furnish health care services to the particular enrollee or to other enrollees.

(2) *Required disenrollment.* Generally, an HMO or CMP must disenroll a Medicare enrollee if he or she—

(i) Moves out of the HMO's or CMP's geographic area;

(ii) Fails to convert to the risk provisions of the HMO's or CMP's Medicare contract;

(iii) Loses entitlement to Medicare Part B benefits; or

(iv) Dies.

(3) *Related provisions.* Specific requirements, limitations, and exceptions are set forth in paragraphs (c) through (i) of this section.

(c) *Failure to pay premiums or other charges.* (1) *Basic rule.* Except as specified in paragraph (c)(2) of this section, an HMO or CMP may disenroll a Medicare enrollee who fails to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, if the HMO or CMP—

(i) Can demonstrate to CMS that it made reasonable efforts to collect the unpaid amount;

(ii) Gives the enrollee written notice of disenrollment, including an explanation of the enrollee's right to a hearing under the HMO's or CMP's grievance procedures; and

(iii) Sends the notice of disenrollment to the enrollee before it notifies CMS.

(2) *Exception.* If the enrollee fails to pay the premium for optional supplemental benefits (that is, a package of benefits that an enrollee is not required to accept), but pays the basic premium and other charges, the HMO or CMP may discontinue the optional benefits but may not disenroll the beneficiary.

(d) *Enrollee commits fraud or permits abuse of the enrollment card.* (1) *Basis for disenrollment.* An HMO or CMP may disenroll a Medicare beneficiary if the beneficiary—

(i) Knowingly provides, on the application form, fraudulent information that materially affects the beneficiary's eligibility to enroll in the HMO or CMP; or

(ii) Intentionally permits others to use his or her enrollment card to obtain services from the HMO or CMP.

(2) *Notice requirement.* If disenrollment is for either of the reasons specified in paragraph (d)(1) of this section, the HMO or CMP must give the beneficiary a written notice of termination of enrollment.

(i) The notice must be mailed to the enrollee before submission of the disenrollment notice to CMS.

(ii) The notice must include an explanation of the enrollee's right to have the disenrollment heard under the grievance procedures established in accordance with §417.436.

(3) *Report to the Inspector General.* The HMO or CMP must report to the Office of the Inspector General of the Department any disenrollment based on fraud or abuse by the enrollee.

(e) *Disenrollment for cause.* (1) *Basis for disenrollment.* An HMO or CMP may disenroll a Medicare enrollee for cause if the enrollee's behavior is disruptive, unruly, abusive, or uncooperative to the extent that his or her continuing enrollment in the HMO or CMP seriously impairs the HMO's or CMP's ability to furnish services to either the particular enrollee or other enrollees.

(2) *Effort to resolve the problem.* The HMO or CMP must make a serious effort to resolve the problem presented by the enrollee, including the use (or attempted use) of internal grievance procedures.

(3) *Consideration of extenuating circumstances.* The HMO or CMP must ascertain that the enrollee's behavior is not related to the use of medical services or to mental illness.

(4) *Documentation.* The HMO or CMP must document the problems, efforts, and medical conditions as described in paragraphs (e)(1) through (e)(3) of this section.

(5) *CMS review of an HMO's or CMP's proposed disenrollment for cause.* (i) CMS decides on the basis of review of the documentation submitted by the HMO or CMP, whether disenrollment requirements have been met.

(ii) CMS makes this decision within 20 working days after receipt of the documentation material, and notifies the HMO or CMP within 5 working days after making its decision.

(6) *Effective date of disenrollment.* If CMS permits an HMO or CMP to disenroll an enrollee for cause, the disenrollment takes effect on the first day of the calendar month after the month in which the HMO or CMP gives the enrollee a written notice of disenrollment that meets the requirements set forth in paragraphs (d)(2)(i) and (d)(2)(ii) of this section.

(f) *Enrollee moves out of the HMO's or CMP's geographic area.* (1) *Basic rules.* (i) *Disenrollment.* Except as provided in paragraph (f)(2) of this section, an HMO

or CMP must disenroll a Medicare enrollee who moves out of its geographic area if the HMO or CMP establishes, on the basis of a written statement from the enrollee, or other evidence acceptable to CMS, that the enrollee has permanently moved out of its geographic area.

(ii) *Notice requirement.* The HMO or CMP must comply with the notice requirements set forth in paragraph (d)(2) of this section.

(iii) *Effect on geographic area.* Failure to disenroll an enrollee who has moved out of the HMO's or CMP's geographic area does not expand that area to encompass the location of the enrollee's new residence.

(2) *Exception.* An HMO or CMP may retain a Medicare enrollee who is absent from its geographic area for an extended period, but who remains within the United States as defined in § 400.200 of this chapter if the enrollee agrees. For purposes of this exception, the following provisions apply:

(i) An absence for an extended period means an uninterrupted absence from the HMO's or CMP's geographic area for more than 90 days but less than 1 year.

(ii) The HMO or CMP and the enrollee may mutually agree upon restrictions for obtaining services while the enrollee is absent for an extended period from the HMO's or CMP's geographic area. However, restrictions may not be imposed on the scope of services described in § 417.440.

(iii) HMOs and CMPs that choose to exercise this exception must make the option available to all Medicare enrollees who are absent for an extended period from their geographic areas. However, HMOs and CMPs may limit this option to enrollees who go to a geographic area served by an affiliated HMO or CMP.

(iv) As used in this paragraph, ''affiliated HMO or CMP'' means an HMO or CMP that—

(A) Is under common ownership or control of the HMO or CMP that seeks to retain the absent enrollees; or

(B) Has in effect an agreement to furnish services to enrollees who are on an extended absence from the geographic area of the HMO or CMP that seeks to retain them.

(v) When the enrollee returns to the HMO's or CMP's geographic area (even temporarily), the restrictions of § 417.448(a) (which limit payment for services not provided or arranged for by the HMO or CMP) apply again immediately.

(vi) If the enrollee fails to return to the HMO's or CMP's geographic area within 1 year from the date he or she left that area, the HMO or CMP must disenroll the beneficiary on the first day of the month following the anniversary of the date the enrollee left that area in accordance with paragraph (f)(1) of this section.

(g) *Failure to convert to risk provisions of Medicare contract.* (1) *Basis for disenrollment.* A risk HMO or CMP must disenroll a nonrisk Medicare enrollee who refuses to convert to the risk provisions of the Medicare contract after CMS determines that all of the HMO's or CMP's nonrisk Medicare enrollees must convert.

(2) *Advance notice requirement.* At least 30 days before it gives CMS notice of disenrollment, the HMO or CMP must give the enrollee written notice of the fact that failure to convert will result in disenrollment.

(h) *Loss of entitlement to Medicare benefits.* (1) *Loss of entitlement to Part A benefits.* If an enrollee loses entitlement to benefits under Part A of Medicare but remains entitled to benefits under Part B, the enrollee automatically continues as a Medicare enrollee of the HMO or CMP and is entitled to receive and have payment made for Part B services, beginning with the month immediately following the last month of his or her entitlement to Part A benefits.

(2) *Loss of entitlement to Part B benefits.* If a Medicare enrollee loses entitlement to Part B benefits, the HMO or CMP must disenroll him or her as a Medicare enrollee effective with the month following the last month of entitlement to Part B benefits. However, the HMO or CMP may continue to enroll the individual under its regular plan if the individual so chooses.

(i) *Death of the enrollee.* Disenrollment is effective with the month following the month of death.

[60 FR 45678, Sept. 1, 1995]

§417.461 Disenrollment by the enrollee.

(a) *Request for disenrollment.* (1) A Medicare enrollee who wishes to disenroll may at any time give the HMO or CMP a signed, dated request in the form and manner prescribed by CMS.

(2) The enrollee may request a certain disenrollment date but it may be no earlier than the first day of the month following the month in which the HMO or CMP receives the request.

(b) *Responsibilities of the HMO or CMP.* The HMO or CMP must—

(1) Submit a disenrollment notice to CMS promptly;

(2) Provide the enrollee with a copy of the request for disenrollment; and

(3) In the case of a risk HMO or CMP, also provide the enrollee with a statement explaining that he or she—

(i) Remains enrolled until the effective date of disenrollment; and

(ii) Until that date, is subject to the restrictions of §417.448(a) under which neither the HMO or CMP nor CMS pays for services not provided or arranged for by the HMO or CMP.

(c) *Effect of failure to submit disenrollment notice to CMS promptly.* If the HMO or CMP fails to submit timely the correct and complete notice required in paragraph (b)(1) of this section, the HMO or CMP must reimburse CMS for any capitation payments received after the month in which payments would have ceased if the requirement had been met timely.

[60 FR 45679, Sept. 1, 1995]

§417.464 End of CMS's liability for payment: Disenrollment of beneficiaries and termination or default of contract.

(a) *Effect of disenrollment: General rule.* (1) CMS's liability for monthly capitation payments to the HMO or CMP generally ends as of the first day of the month following the month in which disenrollment is effective, as shown on CMS's records.

(2) Disenrollment is effective no earlier than the month immediately after, and no later than the third month after, the month in which CMS receives the disenrollment notice in acceptable form.

(b) *Effect of disenrollment: Special rules.* (1) *Fraud or abuse by the enrollee.* If disenrollment is on the basis of fraud committed or abuse permitted by the enrollee, CMS's liability ends as of the first day of the month in which disenrollment is effective.

(2) *Loss of entitlement to Part B benefits.* If disenrollment is on the basis of loss of entitlement to Part B benefits, CMS's liability ends as of the first day of the month following the last month of Part B entitlement.

(3) *Death of enrollee.* If the enrollee dies, CMS's liability ends as of the first day of the month following the month of death.

(4) *Disenrollment at enrollee's request.* If disenrollment is in response to the enrollee's request, CMS's liability ends as of the first day of the month following the month of termination requested by the enrollee.

(c) *Effect of termination or default of contract.* (1) *Termination of contract.* If the contract between CMS and the HMO or CMP is terminated by mutual consent or by unilateral action of either party, CMS's liability for payments ends as of the first day of the month after the last month for which the contract is in effect.

(2) *Default of contract.* If the HMO or CMP defaults on the contract before the end of the contract year because of bankruptcy or other reasons, CMS—

(i) Determines the month in which its liability for payments ends; and

(ii) Notifies the HMO or CMP and all affected Medicare enrollees as soon as practicable.

[60 FR 45680, Sept. 1, 1995]

Subpart L—Medicare Contract Requirements

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§417.470 Basis and scope.

(a) *Basis.* This subpart implements those portions of section 1857(e)(2) of the Act pertaining to cost sharing in enrollment-related costs and section 1876(c), (g), (h), and (i) of the Act that pertain to the contract between CMS and an HMO or CMP for participation in the Medicare program.

(b) *Scope*. This subpart sets forth—

(1) Specific contract requirements; and

(2) Procedures for renewal, nonrenewal, or termination of a contract.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 62 FR 63673, Dec. 2, 1997]

§ 417.472 Basic contract requirements.

(a) *Submittal of contract*. An HMO or CMP that wishes to contract with CMS to furnish services to Medicare beneficiaries must submit a signed contract that meets the requirements of this subpart and any other requirements established by CMS.

(b) *Agreement to comply with regulations and instructions*. The contract must provide that the HMO or CMP agrees to comply with all the applicable requirements and conditions set forth in this subpart and in general instructions issued by CMS.

(c) *Other contract provisions*. In addition to the requirements set forth in §§ 417.474 through 417.488, the contract must contain any other terms and conditions that CMS requires to implement section 1876 of the Act.

(d) *Exemption from Federal procurement regulations*. The Federal Acquisition Regulations and HHS Acquisition Regulations contained in title 48 of the Code of Federal Regulations do not apply to Medicare contracts under section 1876 of the Act.

(e) *Compliance with civil rights laws*. The HMO or CMP must comply with title VI of the Civil Rights Act of 1964 (regulations at 45 CFR part 80), section 504 of the Rehabilitation Act of 1973 (regulations at 45 CFR part 84), and the Age Discrimination Act of 1975 (regulations at 45 CFR part 91).

(f) *Requirements for advance directives*. The HMO or CMP must meet all the requirements for advance directives at § 417.436(d).

(g) *Authority to waive conflicting contract requirements*. Under section 1876(i)(5) of the Act, CMS is authorized to administer the terms of this subpart without regard to provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if it determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(h) *Collection of fees from risk HMOs and CMPs*. (1) The rules set forth in § 422.10 of this chapter for M+C plans also apply to collection of fees from risk HMOs and CMPs.

(2) In applying the part 422 rules, references to ''M+C organizations'' or ''M+C plans'' must be read as references to ''risk HMOs and CMPs''.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 57 FR 8202, Mar. 6, 1992; 58 FR 38079, July 15, 1993; 60 FR 45680, Sept. 1, 1995; 63 FR 35067, June 26, 1998]

§ 417.474 Effective date and term of contract.

(a) *Effective date*. The contract must specify its effective date, which may not be earlier than the date it is signed by both CMS and the HMO or CMP.

(b) *Term*. The contract must specify the duration of its term as follows:

(1) For the initial term, at least 12 months, but no more than 23 months.

(2) For any subsequent term, 12 months.

[60 FR 45680, Sept. 1, 1995]

§ 417.476 Waived conditions.

If CMS waives any of the qualifying conditions required under subpart J of this part, the contract must specify the following information for each waived condition:

(a) The specific terms of the waiver.

(b) The expiration date of the waiver.

(c) Any other information required by CMS.

[60 FR 45680, Sept. 1, 1995]

§ 417.478 Requirements of other laws and regulations.

The contract must provide that the HMO or CMP agrees to comply with—

(a) The requirements for QIO review of services furnished to Medicare enrollees as set forth in subchapter D of this chapter;

(b) Sections 1318(a) and (c) of the PHS Act, which pertain to disclosure of certain financial information;

(c) Section 1301(c)(8) of the PHS Act, which relates to liability arrangements to protect enrollees of the HMO or CMP; and

(d) The reporting requirements in §417.126(a), which pertain to the monitoring of an HMO's or CMP's continued compliance.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, 38082, July 15, 1993]

§417.479 Requirements for physician incentive plans.

(a) The contract must specify that an HMO or CMP may operate a physician incentive plan only if—

(1) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to an individual enrollee; and

(2) The stop-loss protection, enrollee survey, and disclosure requirements of this section are met.

(b) *Applicability*. The requirements in this section apply to physician incentive plans between HMOs and CMP and individual physicians or physician groups with which they contract to provide medical services to enrollees. The requirements in this section also apply to subcontracting arrangements as specified in §417.479(i). These requirements apply only to physician incentive plans that base compensation (in whole or in part) on the use or cost of services furnished to Medicare beneficiaries or Medicaid recipients.

(c) *Definitions*. For purposes of this section:

Bonus means a payment an HMO or CMP makes to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold.

Capitation means a set dollar payment per patient per unit of time (usually per month) that an organization pays a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the physician's own services, referral services, or all medical services.

Payments means any amounts the HMO or CMP pays physicians or physician groups for services they furnish directly, plus amounts paid for administration and amounts paid (in whole or in part) based on use and costs of referral services (such as withhold amounts, bonuses based on referral levels, and any other compensation to the physician or physician group to influence the use of referral services). Bonuses and other compensation that are not based on referral levels (such as bonuses based solely on quality of care furnished, patient satisfaction, and participation on committees) are not considered payments for purposes of this section.

Physician group means a partnership, association, corporation, individual practice association, or other group that distributes income from the practice among members. An individual practice association is a physician group only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement between an HMO or CMP and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished to Medicare beneficiaries or Medicaid recipients enrolled in the HMO or CMP.

Referral services means any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not furnish directly.

Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a physician incentive plan without being at substantial financial risk.

Withhold means a percentage of payments or set dollar amounts that an HMO or CMP deducts from a physician's service fee, capitation, or salary payment, and that may or may not be returned to the physician, depending on specific predetermined factors.

(d) *Prohibited physician payments*. No specific payment of any kind may be made directly or indirectly under the incentive plan to a physician or physician group as an inducement to reduce or limit covered medically necessary services covered under the HMO's or CMP's contract furnished to an individual enrollee. Indirect payments include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(e) *General rule: Determination of substantial financial risk.* Substantial financial risk occurs when the incentive arrangements place the physician or physician group at risk for amounts beyond the risk threshold, if the risk is based on the use or costs of referral services. Amounts at risk based solely on factors other than a physician's or physician group's referral levels do not contribute to the determination of substantial financial risk. The risk threshold is 25 percent.

(f) *Arrangements that cause substantial financial risk.* For purposes of this paragraph, *potential payments* means the maximum anticipated total payments (based on the most recent year's utilization and experience and any current or anticipated factors that may affect payment amounts) that could be received if use or costs of referral services were low enough. The following physician incentive plans cause substantial financial risk if risk is based (in whole or in part) on use or costs of referral services and the patient panel size is not greater than 25,000 patients:

(1) Withholds greater than 25 percent of potential payments.

(2) Withholds less than 25 percent of potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of potential payments.

(3) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(4) Withholds plus bonuses if the withholds plus bonuses equal more than 25 percent of potential payments. The threshold bonus percentage for a particular withhold percentage may be calculated using the formula—

Withhold = 0.75 (Bonus %) + 25%.

(5) Capitation, arrangements, if—

(i) The difference between the maximum potential payments and the minimum potential payments is more than 25 percent of the maximum potential payments; or

(ii) The maximum and minimum potential payments are not clearly explained in the physician's or physician group's contract.

(6) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(g) *Requirements for physician incentive plans that place physicians at substantial financial risk.* HMOs and CMPs that operate incentive plans that place physicians or physician groups at substantial financial risk must do the following:

(1) Conduct enrollee surveys. These surveys must—

(i) Include either all current Medicare/Medicaid enrollees in the HMO or CMP and those who have disenrolled (other than because of loss of eligibility in Medicaid or relocation outside the HMO's or CMP's service area) in the past 12 months, or a sample of these same enrollees and disenrollees;

(ii) Be designed, implemented, and analyzed in accordance with commonly accepted principles of survey design and statistical analysis;

(iii) Address enrollees/disenrollees satisfaction with the quality of the services provided and their degree of access to the services; and

(iv) Be conducted no later than 1 year after the effective date of the Medicare contract and at least annually thereafter.

(2) Ensure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with the following requirements:

(i) If aggregate stop-loss protection is provided, it must cover 90 percent of the costs of referral services (beyond allocated amounts) that exceed 25 percent of potential payments.

(ii) If the stop-loss protection provided is based on a per-patient limit, the stop-loss limit per patient must be determined based on the size of the patient panel and may be a single combined limit or consist of separate limits for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (h)(2) of this section. Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient limit. The per-patient stop-loss limit is as follows:

Panel size	Single combined limit	Separate institutional limit	Separate professional limit
1–1000	$6,000	$10,000	$3,000
1,001–5000	30,000	40,000	10,000
5,001–8,000	40,000	60,000	15,000
8,001–10,000	75,000	100,000	20,000
10,001–25,000	150,000	200,000	25,000
>25,000	none	none	none

(h) *Disclosure and other requirements for organizations with physician incentive plans.*—(1) Disclosure to CMS. Each health maintenance organization or competitive medical plan must provide to CMS information concerning its physician incentive plans as requested.

(2) *Pooling of patients.* Pooling of patients is permitted only if—(i) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group;

(ii) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled;

(iii) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled;

(iv) The distribution of payments to physicians from the risk pool is not calculated separately by patient category; and

(v) The terms of the risk borne by the physicians or physician group are comparable for all categories of patients being pooled.

(3) *Disclosure to Medicare beneficiaries.* Each health maintenance organization or competitive medical plan must provide the following information to any Medicare beneficiary who requests it:

(i) Whether the prepaid plan uses a physician incentive plan that affects the use of referral services.

(ii) The type of incentive arrangement.

(iii) Whether stop-loss protection is provided.

(iv) If the prepaid plan was required to conduct a survey, a summary of the survey results.

(i) *Requirements related to subcontracting arrangements*—(1) *Physician groups.* An HMO or CMP that contracts with a physician group that places the individual physician members at substantial financial risk for services they do not furnish must do the following:

(i) Disclose to CMS any incentive plan between the physician group and its individual physicians that bases compensation to the physician on the use or cost of services furnished to Medicare beneficiaries or Medicaid recipients. The disclosure must include the information specified in paragraphs (h)(1)(i) through (h)(1)(vii) of this section and be made at the times specified in paragraph (h)(2) of this section.

(ii) Provide adequate stop-loss protection to the individual physicians.

(iii) Conduct enrollee surveys as specified in paragraph (g)(1) of this section.

(2) *Intermediate entities.* An HMO or CMP that contracts with an entity (other than a physician group) for the provision of services to Medicare beneficiaries must do the following:

(i) Disclose to CMS any incentive plan between the entity and a physician or physician group that bases compensation to the physician or physician group on the use or cost of services furnished to Medicare beneficiaries or Medicaid recipients. The disclosure must include the information required to be disclosed under paragraphs (h)(1)(i) through (h)(1)(vii) of this section and be made at the times specified in paragraph (h)(2) of this section.

(ii) If the physician incentive plan puts a physician or physician group at substantial financial risk for the cost of services the physician or physician group does not furnish—

(A) Meet the stop-loss protection requirements of this subpart; and

(B) Conduct enrollee surveys as specified in paragraph (g)(1) of this section.

(3) For purposes of paragraph (i)(2) of this section, an entity includes, but is not limited to, an individual practice association that contracts with one or

more physician groups and a physician hospital organization.

(j) *Sanctions against the HMO or CMP.* CMS may apply intermediate sanctions, or the Office of Inspector General may apply civil money penalties described at § 417.500, if CMS determines that an HMO or CMP fails to comply with the requirements of this section.

[61 FR 13446, Mar. 27, 1996; 61 FR 46385, Sept. 3, 1996, as amended at 61 FR 69049, Dec. 31, 1996; 68 FR 50855, Aug. 22, 2003]

§ 417.480 Maintenance of records: Cost HMOs and CMPs.

A reasonable cost contract must provide that the HMO or CMP agrees to maintain books, records, documents, and other evidence of accounting procedures and practices that—

(a) Are sufficient to—

(1) Ensure an audit trail; and

(2) Properly reflect all direct and indirect costs claimed to have been incurred under the contract; and

(b) Include at least records of the following:

(1) Ownership, HMO or CMP, and operation of the HMO's or CMP's financial, medical, and other recordkeeping systems.

(2) Financial statements for the current contract period and three prior periods.

(3) Federal income tax or information returns for the current contract period and three prior periods.

(4) Asset acquisition, lease, sale, or other action.

(5) Agreements, contracts, and subcontracts.

(6) Franchise, marketing, and management agreements.

(7) Schedules of charges for the HMO's or CMP's fee-for-service patients.

(8) Matters pertaining to costs of operations.

(9) Amounts of income received by source and payment.

(10) Cash flow statements.

(11) Any financial reports filed with other Federal programs or State authorities.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§ 417.481 Maintenance of records: Risk HMOs and CMPs.

A risk contract must provide that the HMO or CMP agrees to maintain and make available to CMS upon request, books, records, documents, and other evidence of acounting procedures and practices that—

(a) Are sufficient to—

(1) Establish component rates of the ACR for determining additional and supplementary benefits; and

(2) Determine the rates utilized in setting premiums for State insurance agency purposes; and

(b) Include at least any records or financial reports filed with other Federal agencies or State authorities.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§ 417.482 Access to facilities and records.

The contract must provide that the HMO or CMP agrees to the following:

(a) HHS may evaluate, through inspection or other means, the quality, appropriateness, and timeliness of services furnished under the contract to its Medicare enrollees.

(b) HHS may evaluate, through inspection or other means, the facilities of the HMO or CMP when there is reasonable evidence of some need for that inspection.

(c) HHS, the Comptroller General, or their designees may audit or inspect any books and records of the HMO or CMP or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract.

(d) HHS may evaluate, through inspection or other means, the enrollment and disenrollment records for the current contract period and three prior periods, when there is reasonable evidence of some need for that inspection.

(e) In the case of a reasonable cost HMO or CMP to make available for the purposes specified in paragraphs (a), (b), (c), and (d) of this section, its premises, physical facilities, and equipment, its records relating to its Medicare enrollees, the records specified in § 417.480 and any additional relevant information that CMS may require.

(f) That the right to inspect, evaluate, and audit, will extend through three years from the date of the final settlement for any contract period unless—

(1) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the HMO or CMP at least 30 days before the normal disposition date;

(2) There has been a termination, dispute, fraud, or similar fault by the HMO or CMP, in which case the retention may be extended to three years from the date of any resulting final settlement; or

(3) CMS determines that there is a reasonable possibility of fraud, in which case it may reopen a final settlement at any time.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.484 Requirement applicable to related entities.

(a) *Definition*. As used in this section, *related entity* means any entity that is related to the HMO or CMP by common ownership or control and—

(1) Performs some of the HMO's or CMP's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the HMO or CMP at a cost of more than $2,500 during a contract period.

(b) *Requirement*. The contract must provide that the HMO or CMP agrees to require all related entities to agree that—

(1) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent books, documents, papers, and records of the subcontractor involving transactions related to the subcontract; and

(2) The right under paragraph (b)(1) of this section to information for any particular contract period will exist for a period equivalent to that specified in § 417.482(f).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.486 Disclosure of information and confidentiality.

The contract must provide that the HMO or CMP agrees to the following:

(a) To submit to CMS—

(1) All financial information required under subpart O of this part and for final settlement; and

(2) Any other information necessary for the administration or evaluation of the Medicare program.

(b) To comply with the requirements set forth in part 420, subpart C, of this chapter pertaining to the disclosure of ownership and control information.

(c) To comply with the requirements of the Privacy Act, as implemented by 45 CFR part 5b and subpart B of part 401 of this chapter, with respect to any system of records developed in performing carrier or intermediary functions under §§ 417.532 and 417.533.

(d) To meet the confidentiality requirements of § 482.24(b)(3) of this chapter for medical records and for all other enrollee information that is—

(1) Contained in its records or obtained from CMS or other sources; and

(2) Not covered under paragraph (c) of this section.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§ 417.488 Notice of termination and of available alternatives: Risk contract.

A risk contract must provide that the HMO or CMP agrees to give notice as follows if the contract is terminated:

(a) At least 60 days before the effective date of termination, to give its Medicare enrollees a written notice that—

(1) Specifies the termination date; and

(2) Describes the alternatives available for obtaining Medicare services after termination.

(b) To pay the cost of the written notices.

[60 FR 45680, Sept. 1, 1995]

§ 417.490 Renewal of contract.

A contract with an HMO or CMP is renewed automatically for the next 12-month period unless CMS or the HMO

or CMP decides not to renew, in accordance with § 417.492.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.492 Nonrenewal of contract.

(a) *Nonrenewal by the HMO or CMP.* (1) If an HMO or CMP does not intend to renew its contract, it must—

(i) Give written notice to CMS at least 90 days before the end of the current contract period;

(ii) Notify each Medicare enrollee by mail at least 60 days before the end of the contract period; and

(iii) Notify the general public at least 30 days before the end of the contract period, by publishing a notice in one or more newspapers of general circulation in each community or county located in the HMO's or CMP's geographic area.

(2) CMS may accept a nonrenewal notice submitted less than 90 days before the end of a contract period if—

(i) The HMO or CMP notifies its Medicare enrollees and the public in accordance with paragraph (a)(1) of this section; and

(ii) Acceptance would not otherwise jeopardize the effective and efficient administration of the Medicare program.

(b) *Nonrenewal by CMS.* (1) *Notice of nonrenewal.* If CMS decides not to renew a contract, it gives written notice of nonrenewal as follows:

(i) To the HMO or CMP at least 90 days before the end of the contract period.

(ii) To the HMO's or CMP's Medicare enrollees at least 60 days before the end of the contract period.

(iii) To the general public at least 30 days before the end of the contract period.

(2) *Notice of appeal rights.* CMS gives the HMO or CMP written notice of its right to appeal the nonrenewal decision, in accordance with subpart R of this part, if CMS's decision was based on any of the reasons specified in § 417.494(b).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995]

§ 417.494 Modification or termination of contract.

(a) *Modification or termination by mutual consent.* (1) CMS and an HMO or CMP may modify or terminate a contract at any time by written mutual consent.

(2) If the contract is modified, the HMO or CMP must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification.

(3) If the contract is terminated, the HMO or CMP must notify its Medicare enrollees, and CMS notifies the general public, at least 30 days before the termination date.

(b) *Termination by CMS.* (1) CMS may terminate a contract for any of the following reasons:

(i) The HMO or CMP has failed substantially to carry out the terms of the contract.

(ii) The HMO or CMP is carrying out the contract in a manner that is inconsistent with the effective and efficient implementation of section 1876 of the Act.

(iii) The HMO or CMP has failed substantially to comply with the composition of enrollment requirements specified in § 417.413(d).

(iv) CMS determines that the HMO or CMP no longer meets the requirements of section 1876 of the Act and this subpart for being an HMO or CMP.

(2) If CMS decides to terminate a contract, it sends a written notice informing the HMO or CMP of its right to appeal the termination in accordance with subpart R of this part.

(3) An HMO or CMP with a risk contract must notify its Medicare enrollees of the termination as described in § 417.488.

(4) CMS notifies the HMO's or CMP's Medicare enrollees and the general public of the termination at least 30 days before the effective date of termination.

(c) *Termination by the HMO or CMP.* The HMO or CMP may terminate the contract if CMS has failed substantially to carry out the terms of the contract.

(1) The HMO or CMP must notify CMS at least 90 days before the effective date of the termination and must

include in its notice the reasons for the termination.

(2) The HMO or CMP must notify its Medicare enrollees of the termination at least 60 days before the termination date. Risk HMOs or CMPs must also provide a written description of alternatives available for obtaining Medicare services after termination of the contract. The HMO or CMP is responsible for the cost of these notices.

(3) The HMO or CMP must notify the general public of the termination at least 30 days before the termination date.

(4) The contract is terminated effective 60 days after the HMO or CMP mails the notice to Medicare enrollees as required in paragraph (c)(2) of this section.

(5) CMS's liability for payment ends as of the first day of the month after the last month for which the contract is in effect.

[50 FR 1346, Jan. 10, 1985, as amended at 52 FR 22322, June 11, 1987; 56 FR 46571, Sept. 13, 1991; 58 FR 38079, 38082, July 15, 1993; 60 FR 45681, Sept. 1, 1995]

§417.500 Sanctions against HMOs and CMPs.

(a) *Basis for imposition of sanctions.* CMS may impose the intermediate sanctions specified in paragraph (d) of this section, as an alternative to termination of contract, if CMS determines that an HMO or CMP does one or more of the following:

(1) Fails substantially to provide the medically necessary services required to be provided to a Medicare enrollee and the failure adversely affects (or has a substantial likelihood of adversely affecting) the enrollee.

(2) Requires Medicare enrollees to pay amounts in excess of premiums permitted.

(3) Acts, in violation of the provisions of subpart K of this part, to expel or to refuse to reenroll an individual.

(4) Engages in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by subpart K of this part) by eligible individuals whose medical conditions or histories indicate a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes under this part to CMS, an individual, or to any other entity.

(6) Fails to comply with the requirements of section 1876(g)(6)(A) of the Act relating to the prompt payment of claims.

(7) Fails to meet the requirement in section 1876(f)(1) of the Act that not more than 50 percent of the organization's enrollment be Medicare beneficiaries and Medicaid recipients.

(8) Has a Medicare risk contract and—

(i) Employs or contracts with individuals or entities excluded from participation in Medicare under section 1128 or section 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of those services (directly or indirectly) through an excluded individual or entity.

(9) Fails to comply with the requirements of §§417.479(d) through (i) relating to physician incentive plans.

(b) *Notice of sanction and opportunity to respond.* (1) *Notice of sanction.* Before imposing the intermediate sanctions specified in paragraph (d) of this section, CMS—

(i) Sends a written notice to the HMO or CMP stating the nature and basis of the proposed sanction; and

(ii) Sends the OIG a copy of the notice (other than a notice regarding the restriction on Medicare and Medicaid enrollees as described in paragraph (a)(7) of this section), once the sanction has been confirmed following the notice period or the reconsideration.

(2) *Opportunity to respond.* CMS allows the HMO or CMP 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with a requirement described in paragraph (a) of this section, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the HMO or CMP. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following

the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the HMO's or CMP's conduct poses a threat to an enrollee's health and safety.

(c) *Informal reconsideration.* If, consistent with paragraph (b)(2) of this section, the HMO or CMP submits a timely response to CMS's notice of sanction, CMS conducts an informal reconsideration that:

(1) Consists of a review of the evidence by a CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the HMO or CMP a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(d) *Specific sanctions.* If CMS determines that an HMO or CMP has acted or failed to act as specified in paragraph (a) of this section and affirms this determination in accordance with paragraph (c) of this section, CMS may—

(1) Require the HMO or CMP to suspend acceptance of applications for enrollment made by Medicare beneficiaries during the sanction period;

(2) Suspend payments to the HMO or CMP for Medicare beneficiaries enrolled during the sanction period; and

(3) Require the HMO or CMP to suspend all marketing activities to Medicare enrollees.

(e) *Effective date and duration of sanctions*—(1) *Effective date.* Except as provided in paragraph (e)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the HMO or CMP timely seeks reconsideration under paragraph (c) of this section, on the date specified in the notice of CMS's reconsidered determination.

(2) *Exception.* If CMS determines that the HMO's or CMP's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS's reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the HMO or CMP that CMS is satisfied that the basis for imposing the sanction has been corrected and is not likely to recur.

(f) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (d) of this section, CMS may decline to renew a HMO's or CMP's contract in accordance with § 417.492(b), or terminate the contract in accordance with § 417.494(b).

(g) *Civil money penalties.* If CMS determines that a HMO or CMP has committed an act or failed to comply with a requirement described in paragraph (a) of this section (with the exception of the requirement to limit the percentage of Medicare and Medicaid enrollees described in paragraph (a)(7) of this section), CMS notifies the OIG of that determination. CMS also conveys to the OIG information when it reverses or terminates a sanction imposed under this subpart. In accordance with the provisions of 42 CFR part 1003, the OIG may impose civil money penalties on the HMO or CMP in addition to or in place of the sanctions that CMS may impose under paragraph (d) of this section.

[59 FR 36083, July 15, 1994, as amended at 60 FR 45681, Sept. 1, 1995; 61 FR 13448, Mar. 27, 1996]

Subpart M—Change of Ownership and Leasing of Facilities: Effect on Medicare Contract

§ 417.520 Effect on HMO and CMP contracts.

(a) The provisions set forth in subpart L of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying these provisions, references to ''M+C organizations'' must be read as references to ''HMOs and CMPs''.

(c) In § 422.550, reference to ''subpart K of this part'' must be read as reference to ''subpart L of part 417 of this chapter''.

(d) In § 422.553, reference to ''subpart K of this part'' must be read as reference to ''subpart J of part 417 of this chapter''.

[63 FR 35067, June 26, 1998]

Subpart N—Medicare Payment to HMOs and CMPs: General Rules

§417.524 Payment to HMOs or CMPs: General.

(a) *Basic rule.* The payments that CMS makes to an HMO or CMP under this subpart and subparts O and P of this part for furnishing covered Medicare services are in place of any payment that CMS would otherwise make to a beneficiary or the HMO or CMP under sections 1814(b) and 1833(a) of the Act.

(b) *Basis of payment.* (1) CMS pays the HMOs or CMPs on either a reasonable cost basis or a risk basis depending on the type of contract the HMO or CMP has with CMS.

(2) In certain cases a risk HMO or CMP also receives payments on a reasonable cost basis for certain Medicare enrollees who retain nonrisk status, as provided in §417.444, after the HMO or CMP enters into a risk contract.

[60 FR 46229, Sept. 6, 1995]

§417.526 Payment for covered services.

Subpart O of this part set forth the principles that CMS follows in determining Medicare payment to an HMO or CMP that has a reasonable cost contract. Subpart P of this part describes the per capita method of Medicare payment to HMOs or CMPs that contract on a risk basis.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985; as amended at 58 FR 38080, July 15, 1993; 60 FR 46229, Sept. 6, 1995]

§417.528 Payment when Medicare is not primary payer.

(a) *Limits on payments and charges.* (1) CMS may not pay for services to the extent that Medicare is not the primary payer under section 1862(b) of the Act and part 411 of this chapter.

(2) The circumstances under which an HMO or CMP may charge, or authorize a provider to charge, for covered Medicare services for which Medicare is not the primary payer are stated in paragraphs (b) and (c) of this section.

(b) *Charge to other insurers or the enrollee.* If a Medicare enrollee receives from an HMO or CMP covered services that are also covered under State or Federal worker's compensation, automobile medical, or any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the HMO or CMP may charge, or authorize a provider that furnished the service to charge—

(1) The insurance carrier, employer, or other entity that is liable to pay for these services; or

(2) The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or other entity.

(c) *Charge to group health plans (GHPs) or large group health plans (LGHPs).* An HMO or CMP may charge a GHP or LGHP for covered services it furnished to a Medicare enrollee and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP for these covered services if—

(1) The Medicare enrollee is covered under the plan; and

(2) Under section 1862(b) of the Act, CMS is precluded from paying for the covered services .

(d) *Responsibilities of HMO or CMP.* An HMO or CMP must—

(1) Identify payers that are primary to Medicare under section 1862(b) of the Act;

(2) Determine the amounts payable by these payers; and

(3) Coordinate the benefits of its Medicare enrollees with these payers.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46229, Sept. 6, 1995]

Subpart O—Medicare Payment: Cost Basis

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§417.530 Basis and scope.

This subpart sets forth the principles that CMS follows to determine the amount it pays for services furnished by a cost HMO or CMP to its Medicare enrollees. These principles are based on sections 1861(v) and 1876 of the Act and are, for the most part, the same as those set forth—

(a) In part 412 of this chapter, for paying the costs of inpatient hospital services which, for cost HMOs and CMPs, are considered ''reasonable''

only if they do not exceed the amounts allowed under the prospective payment system; and

(b) In part 413 of this chapter, for the costs of all other covered services.

[60 FR 46230, Sept. 6, 1995]

§ 417.531 Hospice care services.

(a) If a Medicare enrollee of an HMO or CMP with a reasonable cost contract makes an election under § 418.24 of this chapter to receive hospice care services, payment for these services is made to the hospice that furnishes the services in accordance with part 418 of this chapter.

(b) While the enrollee's hospice election is in effect, CMS pays the HMO or CMP on a reasonable cost basis for only the following covered Medicare services furnished to the Medicare enrollee:

(1) Services of the enrollee's attending physician if the physician is an employee or contractor of the HMO or CMP and is not employed by or under contract to the enrollee's hospice.

(2) Services not related to the treatment of the terminal condition for which hospice care was elected or a condition related to the terminal condition.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.532 General considerations.

(a) *Conditions and criteria for payment.* (1) The costs incurred by the HMO or CMP to furnish services covered by Medicare are reimbursable if they are—

(i) Proper and necessary;

(ii) Reasonable in amount; and

(iii) Except as provided in § 417.550, appropriately apportioned among the HMO's or CMP's Medicare enrollees, other enrollees, and nonenrolled patients.

(2) In determining fair and equitable payment for the HMOs or CMPs, CMS generally applies the cost payment principles set forth in § 413.5 of this chapter.

(3) In judging whether costs are reasonable, CMS applies the weighted average of the AAPCCs of each class of the HMO's or CMP's Medicare enrollees (as defined in § 417.582) for the HMO's or CMP's geographic area as an absolute limitation on the total amount payable.

(b) *Method and amount of payment to the HMO or CMP.* (1) CMS makes interim per capita payments each month for each Medicare enrollee, equivalent to the interim per capita cost rate determined in accordance with § 417.570.

(2) CMS adjusts the interim per capita rate as necessary during the contract period and makes final adjustments at the end of the contract period.

(3) In determining the amount due the HMO or CMP, CMS deducts from the reasonable cost actually incurred by the HMO or CMP for covered services furnished to its Medicare enrollees, an amount equal to the actuarial value of the applicable Medicare Part A and Part B deductible and coinsurance amounts that would have applied to the covered services for which payment is being made if these enrollees had not enrolled in the HMO or CMP or another HMO or CMP.

(c) *Election by HMO or CMP.* An HMO or CMP must elect, on an individual provider basis, one of the following methods for payment for hospital and SNF services it furnishes to Medicare enrollees:

(1) Direct payment by CMS.

(2) Direct payment by the HMO or CMP.

(d) *Notice of election.* The election must be made in writing before the beginning of the contract period and is binding for that period.

(e) *Payment by HMO or CMP.* If the HMO or CMP elects to pay providers directly, as provided in paragraph (c) of this section, it must—

(1) Determine the eligibility of its Medicare enrollees to receive covered services through the HMO or CMP;

(2) Make proper coverage decisions and appropriate payments, in accordance with §§ 421.100 and 421.200 of this chapter, for the services furnished to its Medicare enrollees;

(3) Ensure that providers maintain and furnish appropriate documentation of physician certification and recertification, to the extent required under subpart B of part 424 of this chapter; and

(4) Carry out any other procedures required by CMS.

(f) *Review of HMO's or CMP's bill processing capabilities.* If the HMO or CMP elects to pay providers directly, CMS determines whether the HMO or CMP has the experience and capability to carry out the responsibilities specified in paragraph (e) of this section in an efficient and effective manner.

(g) *Direct payment by CMS.* (1) If the HMO or CMP elects to have CMS pay for provider services, CMS pays each provider on a reasonable cost basis or under the PPS system, whichever is appropriate for the particular provider under part 412 or part 413 of this chapter.

(2) In computing the Medicare payment to the HMO or CMP, CMS deducts these payments and any other payments made by the Medicare intermediary or carrier on behalf of the HMO or CMP (such as payment for emergency or urgently needed services under § 417.558).

(h) *Payment for services furnished to Medicare beneficiaries not enrolled in the HMO or CMP.* CMS pays the HMO or CMP for services it furnishes to Medicare beneficiaries who are not its enrollees through the HMO's or CMP's Medicare intermediary or carrier, as appropriate.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 53 FR 6648, Mar. 2, 1988; 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.533 Part B carrier responsibilities.

In paying for Part B services furnished to its enrollees by suppliers, the HMO or CMP must—

(a) Determine the eligibility of individuals to receive those services through the HMO or CMP;

(b) Make proper coverage decisions and appropriate payment as authorized under § 421.200 of this chapter for the services for which its Medicare enrollees are eligible; and

(c) Carry out any other procedures that CMS may require.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.534 Allowable costs.

(a) *Definition—Allowable costs* means the direct and indirect costs, including normal standby costs incurred by the HMO or CMP, that are proper and necessary for efficient delivery of needed health care services. They include the costs of furnishing services to the HMO's or CMP's Medicare enrollees, other enrollees, and nonenrolled patients, which are typical ''provider'' costs, and costs (such as marketing, enrollment, membership, and operation of the HMO or CMP) that are peculiar to health care prepayment organizations.

(b) *Basic rules.* (1) The allowability of an HMO's or CMP's costs for furnishing services is generally determined in accordance with principles applicable to provider costs, as set forth in § 417.536.

(2) The allowability of other costs is determined in accordance with principles set forth in §§ 417.538 through 417.550.

(3) Costs for covered services for which Medicare is not the primary payor, as described in § 417.528, are not allowable.

(c) *Medicare Part D program costs.* To the extent that an HMO or CMP provides qualified prescription drug coverage to enrollees under Part D, no costs related to the offering or provision of Part D benefits are reimbursed under this part. These costs are reimbursed solely under the applicable provisions of part 423 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 70 FR 4525, Jan. 28, 2005]

§ 417.536 Cost payment principles.

(a) *Applicability.* Unless otherwise specified in this subpart, the principles set forth in parts 412 and 413 of this chapter are applicable to the costs incurred by an HMO or CMP or by providers and other facilities owned or operated by the HMO or CMP or related to it by common ownership or control. The most common examples of these costs are set forth in this section.

(b) *Depreciation.* An appropriate allowance for depreciation on buildings and equipment is an allowable cost, in accordance with §§ 413.134, 413.144, and 413.149 of this chapter.

(c) *Interest expense.* Necessary and proper interest on both current and capital indebtedness is an allowable cost, in accordance with § 413.153 of this chapter.

(d) *Cost of educational activities.* An appropriate part of the net cost of approved educational activities of a provider or other health care facility owned or operated by an HMO or CMP is an allowable cost in accordance with § 413.85 of this chapter.

(e) *Compensation of owners.* An appropriate amount of compensation for services of owners is an allowable cost, if the services are actually performed and are necessary, as specified in § 413.102 of this chapter.

(f) *Bad debts.* (1) In accordance with § 413.80 of this chapter, bad debts are deductions from revenue and may be included as allowable costs only if—

(i) They are attributable to Medicare deductible and coinsurance amounts for which the Medicare enrollee is liable; and

(ii) The HMO or CMP has made a reasonable, but unsuccessful, effort to collect those amounts.

(2) If all or part of the deductible and coinsurance amounts is payable through a monthly premium or other periodic payment, the amount allowed as a bad debt may not exceed three times the monthly rate for the actuarial value of the deductible and coinsurance amounts, or its equivalent, if the periodic payment is on other than a monthly basis.

(3) Any bad debt related to a service furnished to a Medicare enrollee of the HMO or CMP, and claimed on a cost report submitted for payment by a provider or other facility reimbursed on a cost basis, may not be claimed as a bad debt by the HMO or CMP.

(g) *Charity and courtesy allowances.* As specified in § 413.80 of this chapter, charity and courtesy allowances are deductions from revenue and may not be included as allowable costs.

(h) *Research costs.* As specified in § 413.90 of this chapter, costs incurred for research purposes, over and above patient care, are not allowable costs.

(i) *Value of services of nonpaid workers.* The value of services of nonpaid workers of an organization is not an allowable cost, except as provided in § 413.94 of this chapter.

(j) *Purchase discounts and allowances and refund of expenses.* Discounts and allowances that an HMO or CMP receives on purchases of goods and services and refunds of previous expense payments must be deducted from the costs to which they relate, in accordance with § 413.98 of this chapter.

(k) *Cost to related entities.* (1) The costs of services, facilities, or supplies furnished to an HMO or CMP by a related entity are allowable at the cost to the related entity in accordance with § 413.17 of this chapter.

(2) An entity is not considered related to the HMO or CMP merely because—

(i) It has a risk or incentive agreement under which the HMO or CMP reimburses or compensates the entity for services it furnishes to the HMOs' or CMPs' enrollees; or

(ii) Substantially all the services the entity furnishes are furnished to the HMO's or CMP's enrollees.

(3) However, an entity described in paragraph (k)(2) of this section and an HMO or CMP are considered related if either of them is in a position to exercise significant management or ownership influence or control over the other.

(l) *Return on equity capital of proprietary providers owned by the HMO or CMP.* An allowance for a reasonable return on equity capital invested and used in providing services is allowable in addition to the reasonable cost of services furnished by a proprietary provider owned by the HMO or CMP. The amount of the allowance is determined in accordance with § 413.157 of this chapter.

(m) *Limitations on payment.* Medicare payment for covered services furnished by entities owned by or operated by, or related to, an HMO or CMP paid on a reasonable cost basis is subject to certain provisions of parts 412 and 413 of this chapter that pertain to reasonable cost and reasonable charge. Those provisions include, but are not necessarily limited to, the following:

(1) For ESRD treatment, the limitations authorized under § 413.170 of this chapter.

(2) For services of physical, occupational, and speech therapists and other therapists and nonphysician health specialists, the limitations set forth in § 413.106 of this chapter.

(3) For drugs, the allowable cost as determined under §§ 405.517 and 410.29 of this chapter.

(4) The overall cost limits established in accordance with § 413.30 of this chapter.

(5) The limitation to the lesser of reasonable cost or customary charges, as set forth in § 413.13 of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 51 FR 34832, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986; 58 FR 38080, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.538 Enrollment and marketing costs.

(a) *Principle*. Costs incurred by an HMO or CMP in performing the enrollment and marketing activities described in subpart k of this part are allowable.

(b) *Included costs*. Allowable enrollment and marketing costs are those necessary and proper costs incurred in offering the HMO's or CMP's plan to potential enrollees in accordance with this part. Those costs include selling, advertising, promotional, and other marketing costs and may not exceed an amount that would be incurred by a prudent and cost-conscious management.

(c) *Application*. Enrollment and marketing costs are allowable, whether incurred directly by HMO or CMP staff or under contract with marketing specialists or other outside consultants.

(d) *Limitation on payment*. The relatively higher costs that an HMO or CMP is likely to incur in initially offering its plan to Medicare beneficiaries are taken into account in determining whether enrollment and marketing costs are reasonable in amount. However, if those costs exceed amounts that would be paid by prudent management, the excess is not allowable.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.540 Enrollment costs.

(a) *Principle*. Enrollment costs are allowable if incurred in maintaining and servicing subscriber contracts for prepayment enrollees.

(b) *Kind of costs included*. Enrollment costs include, but are not limited to, reasonable costs incurred in connection with maintaining statistical, financial, and other data on enrollees.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.542 Reinsurance costs.

Reinsurance costs are not allowable.

§ 417.544 Physicians' services furnished directly by the HMO or CMP.

(a) *Principles*. (1) Compensation paid by an HMO or CMP to physicians is an allowable cost to the extent that it is commensurate with the compensation paid for similar services performed by similar physicians practicing in the same or a similar locality.

(2) Physician compensation may take various forms, but the aggregate compensation allowable must be reasonable in relation to the services personally furnished.

(3) If aggregate physician compensation costs exceed what is normally incurred, the excess is not a reasonable cost.

(b) *Application*. (1) In determining the allowability of the costs of physicians' services, the cost of personal services (for example, expenses attributable to salaries, wages, incentive payments, fringe benefits) must be distinguished from the cost of nonpersonal services (for example, expenses attributable to facilities, equipment, support personnel, supplies).

(2) To be allowable, compensation must be reasonable in relation to the personal services furnished.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.546 Physicians' services and other Part B supplier services furnished under arrangements.

General principle. The amount paid by an HMO or CMP for physicians' services and other Part B supplier services

furnished under arrangements is an allowable cost to the extent it is reasonable. Costs are considered reasonable if they—

(a) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(b) Are comparable to costs incurred for similar services furnished by similar physicians or other suppliers in the same or a similar geographic area.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 34887, July 5, 1995; 60 FR 45372, Aug. 31, 1995]

§ 417.548 Provider services through arrangements.

(a) *Principle*. The cost incurred by an HMO or CMP for covered services furnished under arrangement with a provider is allowable to the extent that it would be allowable and payable under parts 412 and 413 of this chapter, unless the HMO or CMP petitions CMS and demonstrates to HFCA's satisfaction that payment in excess of the amount authorized under parts 412 and 413 of this chapter is justified on the basis of advantages gained by the HMO or CMP.

(b) *Application*. An advantage gained must represent a real and tangible benefit received by the HMO or CMP for the excess cost incurred, and any excess payment is subject to other applicable requirements of parts 405, 412 and 413 of this chapter, including tests of reasonableness.

(c) *Example*. In the case of an arrangement an HMO or CMP has with a provider that is located outside the HMO's or CMP's geographic area and that is not related to the HMO or CMP by common ownership or control, payment of the provider's charges to the HMO or CMP (rather than the payment amounts determined under part 412 or part 413 of this chapter) may be justified in exchange for the advantages of not having to incur the administrative costs of determining the provider's reasonable cost and of making a more timely final settlement with the HMO or CMP. However, repayment of the provider's charges would be acceptable only if—

(1) The provider furnishes services to the HMO's or CMP's enrollees infrequently;

(2) The charges represent an insignificant portion of total Medicare reimbursement to the HMO or CMP; and

(3) The charges do not exceed the customary charges by the provider to its other patients for similar services.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34832, Sept. 30, 1986; 58 FR 38080, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.550 Special Medicare program requirements.

(a) *Principle*. CMS pays the full reasonable cost incurred by an HMO or CMP for activities that are solely for Medicare purposes and unique to Medicare contracts under section 1876 of the Act.

(b) *Application*. CMS pays the full reasonable cost of the following activities:

(1) Reporting increases and decreases in the number of Medicare enrollees.

(2) Obtaining independent certification of the HMO's or CMP's cost report to the extent that it is for Medicare purposes.

(3) Reporting special data that CMS requires solely for program planning and evaluation.

(c) *Prior approval requirement*. The costs specified in paragraph (b) of this section must be separately budgeted and approved by CMS before the contract period begins.

(d) *Limit on full payment*. Full payment is limited to the costs specified in paragraph (b) of this section. All other administrative costs must be apportioned in accordance with § 417.552.

[60 FR 46230, Sept. 6, 1995]

§ 417.552 Cost apportionment: General provisions.

(a) *Basic rule*. The HMO or CMP must apportion its total allowable direct and indirect costs among its Medicare enrollees, its other enrollees, and its nonenrolled patients—

(1) In accordance with this subpart; and

(2) Using methods approved by CMS.

(b) *Purpose of apportionment*. The purpose of apportionment is to ensure that—

(1) The cost of services furnished to Medicare enrollees is not borne by other enrollees and nonenrolled patients; and

(2) The cost of the services furnished to other enrollees and nonenrolled patients is not borne by Medicare.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46230, Sept. 6, 1995]

§ 417.554 Apportionment: Provider services furnished directly by the HMO or CMP.

The Medicare share of the cost of covered services furnished to Medicare enrollees by providers that are owned or operated by the HMO or CMP or are related to the HMO or CMP by common ownership or control must be determined in accordance with the apportionment methods set forth in part 412, §§ 413.24, 413.55, and 415.55 of this chapter.

[51 FR 28574, Aug. 8, 1986, as amended at 51 FR 34832, Sept. 30, 1986; 58 FR 38082, July 15, 1993; 60 FR 46231, Sept. 6, 1995; 60 FR 63189, Dec. 8, 1995]

§ 417.556 Apportionment: Provider services furnished by the HMO or CMP through arrangements with others.

The Medicare share of the cost of covered services furnished to Medicare enrollees through arrangements with providers other than those specified in § 417.554 must be determined as follows:

(a) The Medicare share must be based on the cost the HMO or CMP pays the provider under their arrangement, to the extent that cost is reasonable and within the limits established by §§ 417.534 through 417.548.

(b) Except as specified in paragraph (c) of this section, apportionment must be on the same approved basis that is used by the provider for Medicare beneficiaries who are not Medicare enrollees of the HMO or CMP, subject to the conditions and limitations set forth in § 417.548.

(c) If, because of the special nature or terms of the HMO's or CMP's arrangement with the provider, apportionment on the basis specified in paragraph (b) of this section would result in Medicare's bearing the costs of furnishing services to individuals other than the HMO's or CMP's Medicare enrollees, apportionment must be on another basis that is approved by CMS and that will ensure that Medicare does not pay any of the cost of furnishing services to individuals who are not Medicare enrollees of the HMO or CMP.

(d) If the HMO or CMP elects to have providers reimbursed by the HMO's or CMP's Medicare intermediary, the Medicare share is the amount the intermediary paid the provider.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.558 Emergency, urgently needed, and out-of-area services for which the HMO or CMP accepts responsibility.

(a) *Source of payment.* Either CMS or the HMO or CMP may pay a provider for emergency or urgently needed services or other covered out-of-area services for which the HMO or CMP accepts responsibility.

(b) *Limits on payment.* If the HMO or CMP pays, the payment amount may not exceed the amount that is allowable under part 412 or part 413 of this chapter.

(c) *Exception to limit on payment.* Payment in excess of the limit imposed by paragraph (b) of this section is allowable only if the HMO or CMP demonstrates to CMS's satisfaction that it is justified on the basis of advantages gained by the HMO or CMP, as set forth in § 417.548.

[60 FR 46231, Sept. 6, 1995]

§ 417.560 Apportionment: Part B physician and supplier services.

(a) *Medical services furnished directly by the HMO or CMP.* The total allowable cost of Part B physician and supplier services furnished by employees or partners of the HMO or CMP or by a related entity of the HMO or CMP must be apportioned on the basis of the ratio of covered Part B services furnished to Medicare enrollees to total services furnished to all the HMO's or CMP's enrollees and nonenrolled patients. The HMO or CMP must use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

(b) *Medical services furnished under arrangements made by the HMO or CMP.*

When the HMO or CMP pays for Part B physician and supplier services on some basis other than fee-for-service, the reasonable cost the HMO or CMP pays under its financial arrangement with the physician or supplier must be apportioned between Medicare enrollees and others based on the ratio of covered services furnished to Medicare enrollees to the total services furnished to all enrollees and nonenrolled patients. If apportionment on this basis would result in Medicare bearing the cost of furnishing services to individuals who are not Medicare enrollees, the Medicare share must be determined on another basis (approved by CMS) to ensure that Medicare pays only for services furnished to Medicare enrollees.

(c) *Medical services furnished under an arrangement that provides for the HMO or CMP to pay on a fee-for-service basis.* The Medicare share of the cost of Part B physician and supplier services furnished to Medicare enrollees under arrangements, and paid for by the HMO or CMP on a fee-for-service basis, is determined by multiplying the total amount for all such services by the ratio of charges for covered services furnished to Medicare enrollees to the total charges for all such services.

(d) *Emergency services, urgently needed services, and other covered medical services for which the HMO or CMP assumes financial responsibility.* The Medicare share of the cost of Part B emergency or urgently needed services or other Part B services that are not furnished by a provider and for which the HMO or CMP accepts financial responsibility is determined in accordance with paragraphs (b) and (c) of this section.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 34888, July 5, 1995]

§ 417.564 Apportionment and allocation of administrative and general costs.

(a) *Costs not directly associated with providing medical care.* Enrollment, marketing, and other administrative and general costs that benefit the total enrollment of the HMO or CMP and are not directly associated with furnishing medical care must be apportioned on the basis of a ratio of Medicare enrollees to the total HMO or CMP enrollment.

(b) *Costs significantly related to providing medical services.* (1) The following administrative and general costs, which bear a significant relationship to the services furnished, are not apportioned to Medicare directly; they must be allocated or distributed to the HMO or CMP components and then apportioned to Medicare in accordance with §§ 417.552 through 417.560:

(i) Facility costs.

(ii) Interest expense.

(iii) Medical record costs.

(iv) Centralized purchasing costs.

(v) Accounting and data processing costs.

(vi) Other administrative and general costs that are not included in paragraph (a) of this section.

(2) The allocation or distribution process must be as follows:

(i) If a separate entity or department of an HMO or CMP performs administrative functions the benefit of which can be quantitatively measured (such as centralized purchasing and data processing), the total allowable costs of this entity or department must be allocated or distributed to the components of the HMO or CMP in reasonable proportion to the benefits received by these components.

(ii) If a separate entity or department of an HMO or CMP performs administrative functions the benefit of which cannot be quantitatively measured (such as facility costs), the total allowable costs of this entity or department must be allocated or distributed to the components of the HMO or CMP on the basis of a ratio of total incurred and distributed costs per component to the total incurred and distributed costs for all components.

[60 FR 46231, Sept. 6, 1995]

§ 417.566 Other methods of allocation and apportionment.

(a) *Justification.* A method of apportionment or allocation of costs, other than the methods prescribed in this subpart may be used if it results in a more accurate and equitable apportionment of allowable costs and is justifiable from an administrative and cost standpoint.

(b) *Required approval.* (1) An HMO or CMP that desires to use an alternative method must submit a written request for CMS approval at least 90 days before the beginning of the period for which the different method is to be used.

(2) If CMS approves use of a different method, the HMO or CMP may not revert to another method without first obtaining CMS's approval.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§417.568 Adequate financial records, statistical data, and cost finding.

(a) *Maintenance of records.* (1) An HMO or CMP must maintain sufficient financial records and statistical data for proper determination of costs payable by CMS for covered services the HMO or CMP furnished to its Medicare enrollees either directly or under arrangements with others. These include accurate and sufficient detail of incurred costs and enrollment data.

(2) Unless otherwise provided for in this subpart, the HMO or CMP must follow standardized definitions and accounting, statistics, and reporting practices that are widely accepted in the health care industry.

(b) *Provision of data.* (1) The HMO or CMP must provide adequate cost and statistical data, based on its financial and statistical records, that can be verified by qualified auditors.

(2) The cost data must be based on an approved method of cost finding and, except as provided in paragraph (b)(3) of this section, on the accrual method of accounting.

(3) For governmental institutions that use a cash basis of accounting, cost data developed on this basis is acceptable. However, only depreciation on capital assets, rather than the expenditure for the capital asset, is allowable.

(c) *Provider services furnished directly by the HMO or CMP.* If the HMO or CMP furnishes provider services directly, the provider is subject to the cost-finding and cost-reporting requirements set forth in parts 412 and 413 of this chapter. The provider must use an approved cost-finding method described in §413.24 of this chapter to determine the actual cost of these covered services.

(d) *Supplier services furnished directly by the HMO or CMP.* If the HMO or CMP furnishes Part B physician and supplier services directly, it must furnish statistics that indicate the frequency and type of service provided, in the form and detail prescribed by CMS.

(e) *Part B physician and supplier services furnished through arrangement.* If the HMO or CMP furnishes Part B physician and supplier services under arrangements with others, it must furnish to CMS statistical, financial, and other information with respect to those services in the form and detail prescribed by CMS.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46231, Sept. 6, 1995]

§417.570 Interim per capita payments.

(a) *Principle of payment.* (1) CMS makes monthly advance payments equivalent to the HMO's or CMP's interim per capita rate for each beneficiary who is registered in CMS records as a Medicare enrollee of the HMO or CMP.

(2) Additional lump-sum payments may be made at other times during the contract period, at CMS's discretion, to adjust the total amounts paid during the contract period to the level of incurred costs.

(b) *Determination of rate.* The interim per capita rate of payment is equal to the estimated per capita cost of providing covered services to the HMO's or CMP's Medicare enrollees, based upon the types and components of costs that are reimbursable under this part. The interim per capita rate is determined annually by CMS on the basis of the HMO's or CMP's annual operating and enrollment forecast (as set forth in §417.572) and may be revised during the contract period as explained in paragraphs (c) and (d) of this section.

(c) *Adjustments of payments.* In order to maintain the interim payments at the level of current reasonable costs, CMS will adjust the interim per capita rate, to the extent necessary, on the basis of adequate data supplied by the HMO or CMP in its interim estimated cost and enrollment reports or on other evidence showing that the rate based

on actual costs is more or less than the current rate. Adjustments may also be made if there is—

(1) A change in the number of Medicare enrollees that affects the per capita rate;

(2) A material variation from the costs estimated when the annual operating budget was prepared; or

(3) A significant change in the use of covered services by the HMO's or CMP's Medicare enrollees.

(d) *Reduction of interim payments.* If the HMO or CMP does not submit, on time, the reports and other data required to determine the proper amount of payment, CMS may reduce interim payments to the extent appropriate, or may take any other action authorized under this part. An interim payment reduction remains in effect until CMS can make a reasonable estimate of per capita costs.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.572 Budget and enrollment forecast and interim reports.

(a) *Annual submittal.* The HMO or CMP must submit an annual operating budget and enrollment forecast, in the form and detail required by CMS, at least 90 days before the beginning of each contract period. The forecast must be based on financial and statistical data and records that can be verified if CMS requires a detailed review of supporting records. The data and records include, but are not limited to, all ledgers, books, records, and original evidence of costs, and statistical data used in the determination of reasonable cost.

(b) *Effect of failure to submit on time.* If the HMO or CMP does not submit the budget and enrollment forecast on time, CMS may—

(1) Establish an interim per capita rate of payment on the basis of the best available data and adjust payments on the basis of that rate until the required reports are submitted and a new interim per capita rate can be established; or

(2) If there is not enough data on which to base an interim per capita rate, inform the HMO or CMP that interim payments will not be made until the required reports are submitted.

(c) *Interim cost reports.* (1) An HMO or CMP must submit interim cost reports on a quarterly basis in the form and detail prescribed by CMS. These interim cost reports must be submitted no later than 60 days after the close of each quarter of the contract period.

(2) CMS may reduce the frequency of the reports required under paragraph (c)(1) of this section if CMS determines that, on the basis of the HMO's or CMP's reporting experience, there is good cause to do so.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.574 Interim settlement.

(a) *Determination.* Within 30 days following the receipt of the HMO's or CMP's final interim cost and enrollment reports, CMS will make an interim determination of the estimated amount payable to the HMO or CMP for the reasonable cost of covered services furnished to its Medicare enrollees during the contract period. CMS will base the determination on the interim cost report and enrollment data submitted by the HMO or CMP, and any other relevant data CMS finds appropriate. For this purpose, CMS will accept costs as reported, subject to later review or audit, unless there are obvious errors or inconsistencies.

(b) *Payment.* Any difference between the total amount of interim payments and the amount found payable on the basis of the interim determination under paragraph (a) of this section, must be paid by the HMO or CMP or will be paid by CMS, whichever is appropriate, no later than 30 days after CMS's determination.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 417.576 Final settlement.

(a) *General rule.* Final settlement and payment of amounts due the HMO or CMP or the appropriate Medicare trust funds are made following the HMO's or CMP's submission and CMS's review of an independently certified cost report and supporting documents as described in paragraph (b) of this section.

(b) *Certified cost report as basis for final settlement*—(1) *Timing of cost report.* The HMO or CMP must submit to CMS

an independently certified cost report and supporting documents, in the form and detail required by CMS, no later than 180 days after the end of each contract period, unless CMS extends the period for good cause shown by the HMO or CMP.

(2) *Content of cost report.* The cost report and supporting documents must include the following:

(i) The per capita costs incurred in furnishing covered services to its Medicare enrollees, determined in accordance with subpart O of this part and including—

(A) The costs incurred by entities related to the HMO or CMP by common ownership or control; and

(B) For reports for cost-reporting periods that begin on or after January 1, 1996, the costs of hospital and SNF services paid by Medicare's intermediaries under the option provided by §417.532(d).

(ii) The HMO's or CMP's methods of apportioning cost among Medicare enrollees, and nonenrolled patients, in accordance with the payment procedures specified in this subpart (as, applicable, in parts 412 and 413 of this chapter); and

(iii) Any other information required by CMS.

(3) *Failure to report required financial information.* If the HMO or CMP fails to submit the required cost report and supporting documents within 180 days (or an extended period approved by CMS under paragraph (b)(1) of this section), CMS may—

(i) Consider the failure to report as evidence of likely overpayment; and

(ii) Initiate recovery of amounts previously paid, or reduce interim payments, or both.

(c) *Final determination and adjustment.* (1) After receipt of acceptable reports as specified in paragraph (b) of this section, CMS determines the total payment due the HMO or CMP for furnishing covered services to its Medicare enrollees (which is subject to the audit provisions of this subpart) and makes a retroactive adjustment to bring interim payments into agreement with the payable amount due the HMO or CMP.

(2) A final settlement may be made with the HMO or CMP even though a provider that is not owned or operated by the HMO or CMP or related to the HMO or CMP by common ownership or control and that provides services to the HMO's or CMP's Medicare enrollees has not had a final settlement with CMS under parts 412 and 413 of this chapter for services furnished by the provider to Medicare beneficiaries who are not enrolled in the HMO or CMP. In this situation—

(i) CMS must be satisfied that the costs of covered services furnished to the HMO's or CMP's Medicare enrollees, as shown in the reports specified in paragraph (b) of this section, are reasonable and that the interest of the Medicare program would best be served by not delaying final settlement with the HMO or CMP until there is a final settlement with the provider for services furnished to Medicare beneficiaries not enrolled in the HMO or CMP; and

(ii) Prompt settlement with the HMO or CMP would be in the best interest of the Medicare program if, for instance, the provider's costs represent an insignificant portion of total payment due to the HMO or CMP; or if CMS is satisfied that the provider's costs, as shown in the reports specified in paragraph (b) of this section, will not be modified, to any significant extent, by the final settlement with the provider under parts 412 and 413 of this chapter.

(d) *Notice of amount of payment.* The notice of amount of Medicare payment—

(1) Explains CMS's determination regarding total Medicare payment due the HMO or CMP for the contract period covered by the financial information specified in paragraph (b) of this section;

(2) Relates this determination to the HMO's or CMP's claimed total payable cost for that period;

(3) Explains the amounts and reasons, by appropriate reference to law, regulations, and Medicare program policy and procedures, if the determined amounts differ from the HMO's or CMP's claim; and

(4) Informs the HMO or CMP of its right to a hearing in accordance with subpart R of part 405 of this chapter.

(e) *Basis for retroactive adjustment.*

(1) CMS's determination (as contained in the notice of amount of Medicare payment) constitutes the basis for making retroactive adjustments to any Medicare payment made to the HMO or CMP during the period to which the determination applies.

(2) Further payments to the HMO or CMP may be withheld or offset in order to recover, or to aid in the recovery of, any overpayment identified in the determination as having been made to the HMO or CMP, even if the HMO or CMP requests a hearing under subpart R of part 405 of this chapter.

(3) Any withholding continues until the earliest of the following occurs:

(i) The overpayment is liquidated.

(ii) The HMO or CMP enters into an agreement with CMS to refund the overpaid amount.

(iii) CMS, on the basis of subsequently acquired information, determines that there was no overpayment.

(iv) The decision of a hearing specified in paragraph (d)(4) of this section is that there was no overpayment.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986; 58 FR 38082, July 15, 1993; 60 FR 34888, July 5, 1995; 60 FR 46231, Sept. 6, 1995]

Subpart P—Medicare Payment: Risk Basis

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.580 Basis and scope.

(a) *Basis*. This subpart implements those portions of section 1876 (a), (e), and (g) of the Act that pertain to the amount CMS pays an organization for its Medicare enrollees who are enrolled on a risk basis.

(b) *Scope*. This subpart sets forth—

(1) Method of payment;

(2) Procedures for determining the HMO's or CMP's payment rate; and

(3) Procedures for determining the additional benefits (and their value) the HMO or CMP must provide to its Medicare enrollees.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46231, Sept. 6, 1995]

§ 417.582 Definitions.

As used in this subpart—

AAPCC stands for adjusted average per capita cost.

ACR stands for adjusted community rate.

Actuarial factors means factors such as the age, sex, and disability level distribution of the population and any other relevant factors that CMS determines have a significant effect on the level of utilization and cost of health services.

APCRP stands for average of per capita rates of payment.

Class of Medicare enrollees means a group of Medicare enrollees of an HMO or CMP that CMS constructs on the basis of actuarial factors.

Similar area means an area similar to the HMO's or CMP's geographic area but free from special characteristics that would distort the determination of the AAPCC.

U.S. per capita incurred cost means the average per capita cost, including intermediary or carrier administrative costs, incurred by Medicare, as determined on an accrual basis, for covered services furnished to Medicare beneficiaries nationwide during the most recent period for which CMS has complete data.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§ 417.584 Payment to HMOs or CMPs with risk contracts.

Except in the circumstances specified in § 417.440(d) for inpatient hospital care, and as provided in § 417.585 for hospice care, CMS makes payment for covered services only to the HMO or CMP.

(a) *Principle of payment*. CMS makes monthly advance payments equivalent to the HMO's or CMP's per capita rate of payment for each beneficiary who is registered in CMS records as a Medicare enrollee of the HMO or CMP.

(b) *Determination of rate*. (1) The annual per capita rate of payment for each class of Medicare enrollees is equal to 95 percent of the AAPCC (as determined under the provisions of § 417.588) for that class of Medicare enrollees.

(2) CMS furnishes each HMO or CMP with its per capita rate of payment for each class of Medicare enrollees not later than 90 days before the beginning of the HMO's or CMP's contract period.

(c) *Adjustments to payments.* If the actual number of Medicare enrollees differs from the estimated number on which the amount of advance monthly payment was based, CMS adjusts subsequent monthly payments to take account of the difference.

(d) *Reduction of payments.* If an HMO or CMP requests a reduction in its monthly payment in accordance with §417.592(b)(2), CMS reduces the amount of payment by the appropriate amount.

(e) *Determination of rate for calendar year 1998.* For calendar year 1998, HMOs or CMPs with risk contracts will be paid in accordance with principles contained in subpart F of part 422 of this chapter.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 52 FR 8901, Mar. 20, 1987; 58 FR 38082, July 15, 1993; 60 FR 46232, Sept. 6, 1995; 63 FR 35067, June 26, 1998]

§417.585 Special rules: Hospice care.

(a) No payment is made to an HMO or CMP on behalf of a Medicare enrollee who has elected hospice care under §418.24 of this chapter except for the portion of the payment applicable to the additional benefits described in §417.592. This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the enrollee resumes normal Medicare coverage.

(b) During the time the election is in effect, the HMO or CMP may bill CMS on a fee-for-service basis (subject to the usual Medicare rules of payment) but only for the following covered Medicare services:

(1) Services of the enrollee's attending physician if the physician is an employee or contractor of the HMO or CMP and is not employed by or under contract to the enrollee's hospice.

(2) Services not related to the treatment of the terminal condition for which the enrollee elected hospice care or a condition related to the terminal condition.

(3) Services furnished after the revocation or expiration of the enrollee's hospice election until the full monthly capitation payments begin again.

(c) Payment for hospice care services furnished to Medicare enrollees of an HMO or CMP is made to the Medicare-participating hospice elected by the enrollee.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§417.588 Computation of adjusted average per capita cost (AAPCC).

(a) *Basic data.* In computing the AAPCC, CMS uses the U.S. per capita incurred cost and adjusts it by the factors specified in paragraph (c) of this section to establish an AAPCC for each class of Medicare enrollees.

(b) *Advance notice to the HMO or CMP.* Before the beginning of a contract period, CMS informs the HMO or CMP of the specific adjustment factors it will use in computing the AAPCC.

(c) *Adjustment factors.* (1) *Geographic.* CMS makes an adjustment to reflect the relative level of Medicare expenditures for beneficiaries who reside in the HMO's or CMP's geographic area (or a similar area). This adjustment is based on reimbursement for Medicare covered services and uses the most accurate and timely data that pertain to the HMO's or CMP's geographic area and that is available to CMS when it makes the determination.

(2) *Enrollment.* CMS makes a further adjustment to remove the cost effect of all area Medicare beneficiaries who are enrolled in the HMO or CMP or another HMO or CMP.

(3) *Age, sex, and disability status.* CMS makes adjustments to reflect the age and sex distribution and the disability status of the HMO's or CMP's enrollees based on Medicare program experience and available data that indicate cost differences that result from those factors.

(4) *Other relevant factors.* If accurate data are available and appropriate, CMS makes adjustments to reflect welfare and institutional status and other relevant factors.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§ 417.590 Computation of the average of the per capita rates of payment.

(a) *Computation by the HMO or CMP.* As indicated in § 417.584(b), before an HMO's or CMP's contract period begins, CMS determines a per capita rate of payment for each class of the HMO's or CMP's Medicare enrollees. In order to determine the additional benefits required under § 417.592, weighted averages of those per capita rates must be computed separately for enrollees entitled to Part A and Part B, and for enrollees entitled only to Part B. Except as provided in paragraph (b) of this section, the HMO or CMP must make the computations.

(b) *Computation by CMS.* If the HMO or CMP claims to have insufficient enrollment experience to make the computations required by paragraph (a) of this section, and CMS agrees with the claim, CMS makes the computations, using the best available information, which may include the enrollment experience of other risk HMOs and CMPs.

[58 FR 38075, July 15, 1993]

§ 417.592 Additional benefits requirement.

(a) *General rules.* (1) An HMO or CMP that has an APCRP (as determined under § 417.590) greater than its ACR (as determined under § 417.594) must elect one of the options specified in paragraph (b) of this section.

(2) The dollar value of the elected option must, over the course of a contract period, be at least equal to the difference between the APCRP and the proposed ACR.

(b) *Options.* (1) *Additional benefits.* Provide its Medicare enrollees with additional benefits in accordance with paragraph (c) of this section.

(2) *Payment reduction.* Request CMS to reduce its monthly payments.

(3) *Combination of additional benefits and payment reduction.* Provide fewer than the additional benefits required under paragraph (b)(1) of this section and request CMS to reduce the monthly payments by the remaining difference between the APCRP and the ACR.

(4) *Combination of additional benefits and withholding in a stabilization fund.* Provide fewer than the additional benefits required under paragraph (b)(1) of this section, and request CMS to withhold in a stabilization fund (as provided in § 417.596) the remaining difference between the APCRP and the ACR.

(c) *Special rules: Additional benefits option.* (1) The HMO or CMP must determine additional benefits separately for enrollees entitled to both Part A and Part B benefits and those entitled only to Part B.

(2) The HMO or CMP may elect to provide additional benefits in any of the following forms—

(i) A reduction in the HMO's or CMP's premium or in other charges it imposes in the form of deductibles or coinsurance.

(ii) Health benefits in addition to the required Part A and Part B covered services.

(iii) A combination of reduced charges and additional benefits.

(d) *Notification to CMS.* (1) The HMO or CMP must give CMS notice of its ACR and its weighted APCRP at least 45 days before its contract period begins.

(2) An HMO or CMP that elects the option of providing additional benefits must include in its submittal—

(i) A description of the additional benefits it will provide to its Medicare enrollees; and

(ii) Supporting evidence to show that the selected benefits meet the requirements of paragraph (a)(2) of this section with respect to dollar value equivalence.

[60 FR 46232, Sept. 6, 1995]

§ 417.594 Computation of adjusted community rate (ACR).

(a) *Basic rule.* Each HMO or CMP must compute its basic rate as follows:

(1) Compute an initial rate in accordance with paragraph (b) of this section.

(2) Adjust and reduce the initial rate in accordance with paragraphs (c) and (d) of this section.

(b) *Computation of initial rates.* (1) The HMO or CMP must compute its initial rate using either of the following systems:

(i) A community rating system as defined in § 417.104(b); or

(ii) A system, approved by CMS, under which the HMO or CMP develops

an aggregate premium for all its enrollees and weights the aggregate by the size of the various enrolled groups that compose its enrollment.

(For purposes of this section, enrolled groups are defined as employee groups or other bodies of subscribers that enroll in the HMO or CMP through payment of premiums.)

(2) Regardless of which method the HMO or CMP uses—

(i) The initial rate must be equal to the premium it would charge its non-Medicare enrollees for the Medicare-covered services;

(ii) The HMO or CMP must compute the rates separately for enrollees entitled to Medicare Part A and Part B and for those entitled only to Part B; and

(iii) The HMO or CMP must identify and take into account anticipated revenue from health insurance payers for those services for which Medicare is not the primary payer as provided in §417.528.

(3) Except as provided in paragraph (b)(4) of this section, the HMO or CMP must identify in its initial rate calculation, the following components whose rates must be consistent with rates used by the HMO or CMP in calculating premiums for non-Medicare enrollees:

(i) Hospital services (services covered under Medicare Part A and Part B shown separately).

(ii) Physicians' services.

(iii) Other medical services (for example, X-ray and laboratory services).

(iv) Home health services.

(v) Out-of-plan claims for emergency services.

(vi) Skilled nursing care services.

(vii) Ambulance services.

(viii) Other Medicare covered services.

(ix) General and administrative.

(x) Noncovered Medicare services (for example, eyeglasses).

(xi) Services for which Medicare is the secondary payer.

(xii) Enrollee liabilities (for example, deductibles, coinsurance, or copayments) for covered services.

(4) An HMO or CMP that does not usually separate its premium components as described in paragraph (b)(3) of this section may calculate its initial rate with the methods it uses for its other enrolled groups if the HMO or CMP provides CMS with the documentation necessary to support any adjustments the HMO or CMP makes to the initial rate in accordance with paragraph (e) of this section.

(5) The initial rate calculation must not carry forward any losses experienced by the HMO or CMP during prior contract periods. The HMO or CMP must submit supporting documentation to assure CMS that rates do not include past losses but only premiums for the price of additional benefits and services of the upcoming contract period.

(c) *Adjustment of initial rates.* (1) *Purpose of adjustment.* The purpose of adjustment is to reflect the utilization characteristics of Medicare enrollees.

(2) *Adjustment by the HMO or CMP.* The HMO or CMP may adjust the rate for a particular service using more than one of the following factors if they do not duplicate each other:

(i) *Unit of service.* If the HMO or CMP purchases or identifies services on a unit of service basis and the unit of service is defined the same for all enrollees, the HMO or CMP may make an adjustment in its initial rate to reflect the number of units of services furnished to its Medicare enrollees in comparison to those furnished to other enrollees.

(ii) *Complexity or intensity of services.* The HMO or CMP may make an adjustment to reflect the differences in the complexity or intensity of services furnished to its Medicare enrollees if the calculation of its initial rate includes the elements of this adjustment.

(3) *Support documentation.* All adjustments made by the HMO or CMP must be accompanied by adequate supporting data. If an HMO or CMP does not have sufficient enrollment experience to develop this data, it may, during its initial contract period, use documented statistics from a nationally recognized statistical source.

(4) *Adjustment by CMS.* If the HMO or CMP does not have adequate data to adjust the initial rate calculated under paragraph (b) of this section to reflect the utilization characteristics of its Medicare enrollees, CMS will, at the HMO's or CMP's request, adjust the initial rate. CMS adjusts the rate on

the basis of differences in the utilization characteristics of—

(i) Medicare and non-Medicare enrollees in other HMOs or CMPs; or

(ii) Medicare beneficiaries (in the HMO's or CMP's area, or State, or the United States) who are eligible to enroll in an HMO or CMP and other individuals in that same area, or State, or the United States.

(d) *Reduction of adjusted rates.* The HMO or CMP or CMS further reduces the adjusted rates by the actuarial value of applicable Medicare deductibles and coinsurance.

(e) *CMS review.* (1) *Submission of data.* The HMO or CMP must submit its ACR and the methodology used to compute it for CMS review and approval, and must include adequate supporting data.

(2) *Appeals procedures.* (i) If CMS determines that an HMO's or CMP's ACR computation is not acceptable, the HMO or CMP may, within 30 days after receipt of notice of the determination, file with CMS a request for a hearing.

(ii) The request must state why the HMO or CMP believes the determination is incorrect, and include any supporting evidence the HMO or CMP considers pertinent.

(iii) A hearing officer designated by CMS conducts the hearing in accordance with the hearing procedures set forth in §§ 405.1819 through 405.1833 of this chapter.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46232, Sept. 6, 1995]

§ 417.596 Establishment of a benefit stabilization fund.

(a) *General.* If an HMO or CMP is required to provide its Medicare enrollees with additional benefits as described in § 417.592, the organization may request that CMS withhold a part of its monthly per capita payment in a benefit stabilization fund. The fund will be used to prevent excessive fluctuation in the provision of those additional benefits in subsequent contract periods.

(b) *Notification to CMS.* An HMO's or CMP's request to have monies withheld in a benefit stabilization fund must be made when the HMO or CMP notifies CMS under § 417.592(d) of its ACR and its APCRP in preparation for its next contract period.

(c) *Limitations on the amounts withheld*—(1) *Limit per contract period.* Except as provided in paragraph (c)(3) of this section, CMS does not withhold in a benefit stabilization fund more than 15 percent of the difference between an HMO's or CMP's ACR and its ACPRP for a given contract period.

(2) *Cumulative limit.* If CMS has established a benefit stabilization fund for an HMO or CMP, it does not approve a request for withholding made by that HMO or CMP for a subsequent contract period that would cause the total value of the benefit stabilization fund to exceed 25 percent of the difference between the HMO's or CMP's ACR and the average of its per capita rates of payment for that subsequent contract period.

(3) *Exception.* CMS may grant an exception to the limit described in paragraph (c)(1) of this section if an HMO or CMP can demonstrate to CMS's satisfaction that the value of the additional benefits it provides to its Medicare enrollees fluctuates substantially in excess of 15 percent from one contract period to another.

(d) *Financial management of benefit stabilization funds.* (1) The amounts withheld by CMS to establish and maintain a benefit stabilization fund are in the custody of the Federal Health Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

(2) The amounts withheld in a benefit stabilization fund are accounted for by CMS in accounts in which interest does not accrue to the HMO or CMP.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended by 56 FR 46571, Sept. 13, 1991; 58 FR 38083, July 15, 1993; 60 FR 46233, Sept. 6, 1995]

§ 417.597 Withdrawal from a benefit stabilization fund.

(a) *Notification to CMS.* An HMO's or CMP's request to make a withdrawal from its benefit stabilization fund for use during a contract period must be made when the HMO or CMP notifies CMS of its ACR and its ACPRP for that contract period. In making its request, the HMO or CMP must—

(1) Indicate how it intends to use the withdrawn amounts;

(2) Justify the need for the withdrawal in terms of stabilizing the additional benefits it provides to Medicare enrollees;

(3) Document the HMO's or CMP's experience with fluctuations of revenue requirements relative to the additional benefits it provides to Medicare enrollees; and

(4) Document its experience during the contract period previous to the one for which it requests withdrawal to ensure that the HMO or CMP will not be using the withdrawn amounts to refinance losses suffered during that previous contract period.

(b) *Criteria for CMS approval.* CMS approves a request for a withdrawal from a benefit stabilization fund for use during the next contract period only if—

(1) The HMO's or CMP's average of its per capita rates of payment for the next contract period is less than that of the previous contract period;

(2) The HMO's or CMP's ACR for the next contract period is significantly higher than that of the previous contract period; or

(3) The HMO's or CMP's revenue requirements for the next contract period for providing the additional benefits it provided during the previous contract period is significantly higher than the requirements for that previous period and the ACR for the next contract period results in an additional benefits package that is less in total value than that of the previous contract period.

(c) *Basis for denial.* CMS does not approve a request for a withdrawal from a benefit stabilization fund if the withdrawal would allow the HMO or CMP to—

(1) Offer without charge the supplemental services it provides to its Medicare enrollees under the provisions of §417.440 (b)(2) or (b)(3); or

(2) Refinance prior contract period losses or to avoid losses in the upcoming contract period.

(d) *Form of payment.* Payment of monies withdrawn from a benefit stabilization fund is made, in equal parts, as an additional amount to the monthly advance payment made to the HMO or CMP under §417.584 during the period of the contract.

[58 FR 38075, July 15, 1993, as amended at 60 FR 46233, Sept. 6, 1995]

§417.598 Annual enrollment reconciliation.

CMS's payment to an HMO or CMP may be subject to an enrollment reconciliation at least annually. CMS conducts this reconciliation as necessary to ensure that the payments made do not exceed or fall short of the appropriate per capita rate of payment for each Medicare enrollee of the HMO or CMP during the contract period. The HMO or CMP must submit any information or reports required by CMS to conduct the reconciliation.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993; 60 FR 46233, Sept. 6, 1995]

Subpart Q—Beneficiary Appeals

§417.600 Basis and scope.

(a) *Statutory basis.* (1) Section 1869 of the Act provides the right to a redetermination, reconsideration, hearing, and judicial review for individuals dissatisfied with a determination regarding their Medicare benefits.

(2) Section 1876 of the Act provides for Medicare payments to HMOs and CMPs that contract with CMS to enroll Medicare beneficiaries and furnish Medicare-covered health care services to them.

(3) Section 234 of the MMA requires section 1876 contractors to operate under the same provisions as MA plans where two plans of the same type enter the cost plan contract's service area.

(b) *Scope.* This subpart sets forth—

(1) The appeals procedures, as required by section 1876(c)(5)(B) of the Act for Medicare enrollees who are dissatisfied with an ''organization determination'' as defined in §417.606;

(2) The applicability of grievance procedures established by the HMO or CMP under section 1876(c)(5)(A) of the Act and §417.604(a) for complaints that do not involve an organization determination;

(3) The responsibility of the HMO or CMP—

(i) To develop and maintain procedures; and

(ii) To ensure all Medicare enrollees have a complete written explanation of their grievance and appeal rights, the availability of expedited reviews, the steps to follow, and the time limits for each procedure; and

(4) The special rules that apply when a beneficiary requests immediate QIO review of a determination that he or she no longer needs inpatient hospital care.

[60 FR 46233, Sept. 6, 1995, as amended at 62 FR 23374, Apr. 30, 1997; 70 FR 4713, Jan. 28, 2005]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.600 was revised effective March 22, 2005, except for paragraph (b), which will become effective January 1, 2006. For the convenience of the user the revised text is set forth as follows:

§ 417.600 Basis and scope.

* * * * *

(b) *Applicability*. (1) The rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(2) In applying those provisions, references to section 1852 of the Act must be read as references to section 1876 of the Act, and references to MA organizations as references to HMOs and CMPs.

§ 417.602 Definitions.

As used in this subpart, unless the context indicates otherwise—

ALJ stands for administrative law judge.

RRB stands for Railroad Retirement Board.

[50 FR 1346, Jan. 10, 1985, and amended at 58 FR 38080, July 15, 1993; 60 FR 46233, Sept. 6, 1995]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.602 was removed, effective January 1, 2006.

§ 417.604 General provisions.

(a) *Responsibilities of the HMO or CMP*. (1) The HMO or CMP must establish and maintain—

(i) Appeals procedures that meet the requirements of this subpart for issues that involve organization determinations; and

(ii) Grievance procedures for dealing with issues that do not involve organization determinations.

(2) The HMO or CMP must ensure that all enrollees receive written information about the grievance and appeals procedures that are available to them.

(b) *Limits on applicability of this subpart*. (1) If an enrollee requests immediate QIO review (as provided in § 417.605) of a determination of noncoverage of inpatient hospital care—

(i) The enrollee is not entitled to subsequent review of that issue under this subpart; and

(ii) The QIO review decision is subject to the appeals procedures set forth in part 473 of this chapter.

(2) Any determination regarding services that were furnished by the HMO or CMP, either directly or under arrangement, for which the enrollee has no further liability for payment are not subject to appeal.

(3) Services included in an optional supplemental plan under (§ 417.440(b)(2)) are subject only to a grievance procedure.

(4) Physicians and other individuals who furnish services under arrangement with an HMO or CMP have no right of appeal under this subpart, except as provided in §§ 417.609(c)(4) and 417.617(c)(4), which allow physicians and other health professionals to act on behalf of an enrollee in time-sensitive situations when an organization determination or reconsideration is being requested.

(c) *Applicability of other regulations*. Unless otherwise provided in this subpart, regulations at 20 CFR, part 404, subparts J and R, (pertaining respectively to conduct of hearings and representation of parties under title II of the Act) are applicable under this subpart.

[60 FR 46233, Sept. 6, 1995, as amended at 62 FR 23374, Apr. 30, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.604 was removed, effective January 1, 2006.

§417.605 Immediate QIO review of a determination of noncoverage of inpatient hospital care.

(a) *Right to review.* A Medicare enrollee who disagrees with a determination made by an HMO, CMP, or a hospital that inpatient care is no longer necessary may remain in the hospital and may (directly or through his or her authorized representative) request immediate QIO review of the determination.

(b) *Procedures.* For the immediate QIO review process, the following rules apply:

(1) The enrollee or authorized representative must submit the request for immediate review—

(i) To the QIO that has an agreement with the hospital under §466.78 of this chapter;

(ii) In writing or by telephone; and

(iii) By noon of the first working day after receipt of the written notice of the determination that the hospital stay is no longer necessary.

(2) On the date it receives the enrollee's request, the QIO must notify the HMO or CMP that a request for immediate review has been filed.

(3) The HMO or CMP must supply any information that the QIO requires to conduct its review and must make it available, by phone or in writing, by the close of business of the first full working day immediately following the day the enrollee submits the request for review.

(4) In response to a request from the HMO or CMP, the hospital must submit medical records and other pertinent information to the QIO by close of business of the first full working day immediately following the day the HMO or CMP makes its request.

(5) The QIO must solicit the views of the enrollee who requested the immediate QIO review (or the enrollee's representative).

(6) The QIO must make a determination and notify the enrollee, the hospital, and the HMO or CMP by close of business of the first working day after it receives the information from the hospital, or the HMO or CMP, or both.

(c) *Financial responsibility.* (1) *General rule.* Except as provided in paragraph (c)(2) of this section, the HMO or CMP continues to be financially responsible for the costs of the hospital stay until noon of the calendar day following the day the QIO notifies the enrollee of its review determination.

(2) *Exception.* The hospital may not charge the HMO or CMP (or the enrollee) if—

(i) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate QIO review; and

(ii) The QIO upholds the noncoverage determination made by the HMO or CMP.

[59 FR 59941, Nov. 21, 1994]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, §417.605 was removed, effective January 1, 2006.

§417.606 Organization determinations.

(a) *Actions that are organization determinations.* An organization determination is any determination made by an HMO or CMP with respect to any of the following:

(1) Payment for emergency or urgently needed services.

(2) Any other health services furnished by a provider or supplier other than the HMO or CMP that the enrollee believes—

(i) Are covered under Medicare; and

(ii) Should have been furnished, arranged for, or reimbursed by the HMO or CMP.

(3) The HMO's or CMP's refusal to provide services that the enrollee believes should be furnished or arranged for by the HMO or CMP and the enrollee has not received the services outside the HMO or CMP.

(4) Discontinuation of a service (such as a skilled nursing facility discharge), if the enrollee disagrees with the determination that the service is no longer medically necessary.

(b) *Actions that are not organization determinations.* The following are not organization determinations for purposes of this subpart:

(1) A determination regarding services that were furnished by the HMO or CMP, either directly or under arrangement, for which the enrollee has no further obligation for payment.

(2) A determination regarding services included in an optional supplemental plan (see §417.440(b)(2)).

(c) *Relation to grievances.* A determination that is not an organization

determination is subject only to a grievance procedure under § 417.436(a)(2).

[59 FR 59942, Nov. 21, 1994, as amended at 62 FR 23374, Apr. 30, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.606 was removed, effective January 1, 2006.

§ 417.608 Notice of adverse organization determination.

(a) If an HMO or CMP makes an organization determination that is partially or fully adverse to the enrollee, it must notify the enrollee of the determination—

(1) Within 60 days of receiving the enrollee's request for payment for services; or

(2) As specified in § 417.609(c)(3) for expedited organization determinations.

(b) The notice must—

(1) State the specific reasons for the determination; and

(2) Inform the enrollee of his or her right to a reconsideration, including the right to and conditions for obtaining an expedited reconsidered determination.

(c) The failure to provide the enrollee with timely notification of an adverse organization determination as specified in paragraph (a) of this section or in § 417.609(b) (concerning time frames for expediting certain organization determinations) constitutes an adverse organization determination and may be appealed.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59942, Nov. 21, 1994; 62 FR 23375, Apr. 30, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.608 was removed, effective January 1, 2006.

§ 417.609 Expediting certain organization determinations.

(a) An enrollee, or an authorized representative of the enrollee, may request that an organization determination as defined in §§ 417.606(a)(3) and (a)(4) be expedited. The request may be made orally to the HMO or CMP.

(b) The HMO or CMP must maintain procedures for expediting organization determinations when, upon request from an enrollee or authorized representative of the enrollee, the organization decides that making the determination according to the procedures and time frames set forth in § 417.608(a)(1) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(c) The procedures must include the following:

(1) Receipt of oral requests, followed by written documentation of the oral requests.

(2) Prompt decision-making regarding whether the request will be expedited, or handled within the standard time frame set forth at § 417.608(a)(1), including notification of the enrollee if the request is not expedited.

(3) Notification of the enrollee, and the physician as appropriate, as expeditiously as the enrollee's health condition requires, but within 72 hours of the request. An extension of up to 10 working days is permitted if requested by the enrollee or if the HMO or CMP finds that additional information is necessary and the delay is in the interest of the enrollee.

(i) Notification must comply with § 417.608(b), concerning the content of a notice of adverse organization determination.

(ii) If the initial notification is not in writing, written confirmation must be mailed to the enrollee within 2 working days.

(iii) In cases for which the HMO or CMP must receive medical information from a physician or provider not affiliated with the HMO or CMP, the time standard begins with receipt of the information.

(4) Granting the request of a physician, regardless of whether the physician is affiliated with the organization or not, to expedite the enrollee's request.

[62 FR 23375, Apr. 30, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.609 was removed, effective January 1, 2006.

§ 417.610 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee;

(b) An assignee of the enrollee (that is, a physician or other supplier who has provided a service to the enrollee

and formally agrees to waive any right to payment from the enrolee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other entity determined to have an appealable interest in the proceeding.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59942, Nov. 21, 1994]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, §417.610 was removed, effective January 1, 2006.

§417.612 Effect of organization determination.

The organization determination is binding on all parties unless it is reconsidered in accordance with §§417.614 through 417.626, or revised in accordance with §417.638.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59941, Nov. 21, 1994; 62 FR 25855, May 12, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, §417.612 was removed, effective January 1, 2006.

§417.614 Right to reconsideration.

Any party who is dissatisfied with an organization determination or with one that has been reopened and revised may request reconsideration of the determination in accordance with the procedures of §417.616, concerning a request for reconsideration, or §417.617, concerning certain expedited reconsiderations.

[62 FR 23375, Apr. 30, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, §417.614 was removed, effective January 1, 2006.

§417.616 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with—(1) The HMO or CMP that made the organization determination;

(2) An SSA office; or

(3) In the case of a qualified railroad retirement beneficiary, an RRB office.

(4) In the case of a request for an expedited reconsideration, as provided for in §417.617 (concerning certain expedited reconsiderations), the HMO or CMP.

(b) *Time for filing a request.* Except as provided in paragraph (c) of this section, the request for reconsideration must be filed within 60 days from the date of the notice of the organization determination.

(c) *Extension of time to file a request.* (1) *Rule.* If good cause is shown, the HMO or CMP that made the organization determination may extend the time for filing the request for reconsideration.

(2) *Method of requesting an extension.* If the time limit in paragraph (b) of this section has expired, a party to the organization determination may file a request for reconsideration with the HMO or CMP, CMS, SSA, or, in the case of qualified railroad retirement beneficiary, and RRB office. The request to extend the time limit must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed timely.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the initial determination as described in §417.610, and any other person or entity whose rights with respect to the initial determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawal of request.* A request for reconsideration may be withdrawn by the party who filed the request. The request for withdrawal must be filed at one of the places specified in paragraph (c)(2) of this section.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 59 FR 59942, Nov. 21, 1994; 62 FR 23375, Apr. 30, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, §417.616 was removed, effective January 1, 2006.

§417.617 Expediting certain reconsiderations.

(a) An enrollee, or an authorized representative of the enrollee, may request that a reconsideration be expedited. The request may be made orally to the HMO or CMP.

(b) The HMO or CMP must maintain procedures for expediting reconsiderations when, upon request from an enrollee or an authorized representative

of the enrollee, the organization decides that the longer time frames permitted in § 417.620(c) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(c) The procedures must comply with the requirements for reconsidered determinations set forth in §§ 417.614 through 417.626 and include the following items:

(1) Receipt of oral requests, followed by written documentation of the oral requests.

(2) Prompt decision-making regarding whether the request will be expedited or handled within the standard time frame of § 417.620(c), including notification of the enrollee if the request is not expedited.

(3) Notification of the enrollee, and the physician as appropriate, as expeditiously as the enrollee's health condition requires, but within 72 hours of the request. An extension of up to 10 working days is permitted if requested by the enrollee or if the HMO or CMP finds that additional information is necessary and the delay is in the interest of the enrollee.

(i) Notification must comply with § 417.624(b), concerning the content of a notice of a reconsidered determination.

(ii) If the initial notification is not in writing, written confirmation must be mailed to the enrollee within 2 working days.

(iii) In cases for which the HMO or CMP must receive medical information from a physician or provider not affiliated with the HMO or CMP, the time standard begins with receipt of the information.

(4) Granting the request of a physician, regardless of whether the physician is affiliated with the organization or not, to expedite the request.

[62 FR 23375, Apr. 30, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.617 was removed, effective January 1, 2006.

§ 417.618 Opportunity to submit evidence.

The HMO or CMP must provide the parties to the reconsideration reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited reconsideration, the opportunity to present evidence is limited by the short time frames for making decisions, and the organization must inform the enrollee, or the authorized representative of the enrollee, of the conditions for submitting the evidence.

[62 FR 23375, Apr. 30, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.618 was removed, effective January 1, 2006.

§ 417.620 Responsibility for reconsiderations; time limits.

(a) If the HMO or CMP can make a reconsidered determination that is completely favorable to the enrollee, the HMO or CMP issues the reconsidered determination.

(b) If the HMO or CMO recommends partial or complete affirmation of its adverse determination, the HMO or CMP must prepare a written explanation and send the entire case to HFCA. CMS makes the reconsidered datermination.

(c) The HMO or CMP must issue the reconsidered determination to the enrollee, or submit the explanation and file to CMS within 60 calendar days from the date of receipt of the request for reconsideration. In the case of an expedited reconsideration, the HMO or CMP must issue the reconsidered determination as specified in § 417.617(c)(3) or submit the explanation and file to CMS within 24 hours of its determination, the expiration of the 72-hour review period, or the expiration of the extension.

(d) For good cause shown, CMS may allow extensions to the time limit set forth in paragraph (c) of this section.

(e) Failure by the HMO or CMP to provide the enrollee with a reconsidered determination within the time limits described in paragraph (c) of this section or to obtain a good cause extension described in paragraph (d) of this section constitutes an adverse determination, and the HMO or CMP must submit the file to CMS.

(f) If the HMO or CMP refers the matter to CMS, it must concurrently notify the beneficiary of that action.

[59 FR 59942, Nov. 21, 1994, as amended at 62 FR 23376, Apr. 30, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.620 was removed, effective January 1, 2006.

§ 417.622 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the organization determination, the evidence and findings upon which it was based, and any other evidence submitted by the parties or obtained by CMS or the HMO or CMP; and

(b) Is made by a person or persons who were not involved in making the organization determination.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59941, 59942, Nov. 21, 1994]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.622 was removed, effective January 1, 2006.

§ 417.624 Notice of reconsidered determination.

(a) *Responsibility for notice.* The entity that makes the reconsidered determination is responsible for mailing notice to the parties and, if that entity is not CMS, for sending a copy to CMS.

(b) *Content of notice.* The notice must—

(1) State the specific reasons for the reconsidered determination;

(2) Inform the party of his or her right to a hearing if the amount in controversy is $100 or more; and

(3) Describe the procedures that the party must follow to obtain a hearing.

[50 FR 1346, Jan. 10, 1985]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.624 was removed, effective January 1, 2006.

§ 417.626 Effect of reconsidered determination.

A reconsidered determination is binding on all parties unless a request for a hearing is filed in accordance with the provisions of § 417.632, or unless it is revised in accordance with § 417.638.

[50 FR 1346, Jan. 10, 1985, as amended at 62 FR 25855, May 12, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.626 was removed, effective January 1, 2006.

§ 417.630 Right to a hearing.

If the amount remaining in controversy is $100 or more, any party to the reconsideration who is dissatisfied with the reconsidered determination has a right to a hearing. (The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with § 405.740 of this chapter for Part A services and § 405.820(b) of this chapter for Part B services. If the basis for the appeal is the refusal of services, the projected value of those services is used in computing the amount remaining in controversy.)

[59 FR 59942, Nov. 21, 1994]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.630 was removed, effective January 1, 2006.

§ 417.632 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed at one of the places specified in § 417.616(a).

(b) *Time for filing a request.* Except when the time is extended by an ALJ as provided in 20 CFR 404.933(c), a request for a hearing must be filed within 60 days of the date of the notice of reconsidered determination.

(c) *Parties to a hearing.* (1) The parties to a hearing must be the parties to the reconsideration and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(2) The HMO or CMP must be made a party to the hearing but does not have a right to request a hearing.

(d) *ALJ action when the amount in controversy is less than $100.* (1) If the request plainly shows that the amount in controversy is less than $100, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than $100, he or she discontinues the hearing and does not rule on the substantive issues raised in the appeal.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 60 FR 46234, Sept. 6, 1995; 62 FR 25855, May 12, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.632 was removed, effective January 1, 2006.

§ 417.634 Departmental Appeals Board (DAB) review.

Any party to the hearing, including the HMO or CMP, who is dissatisfied with the hearing decision, may request the DAB to review the ALJ's decision or dismissal. Regulations beginning at 20 CFR 404.967 regarding SSA Appeals Council Review are applicable to DAB review for matters addressed by this subpart.

[62 FR 25855, May 12, 1997]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.634 was removed, effective January 1, 2006.

§ 417.636 Court review.

(a) *Review of ALJ's decision.* A party or the HMO or CMP may request judicial review of an ALJ's decision if—

(1) The Departmental Appeals Board denied the party's or the HMO's or CMP's request for review; and

(2) The amount in controversy is $1,000 or more.

(b) *Review of Departmental Appeals Board decision.* A party or the HMO or CMP may request judicial review of the Departmental Appeals Board decision if—

(1) It is the final decision of CMS; and

(2) The amount in controversy is $1,000 or more.

(c) *Request for review.* The civil action must be filed in a district court of the United States in accordance with section 205(g) of the Act (see 20 CFR 422.210 for a description of the procedures to follow in requesting judicial review).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 61 FR 32348, June 24, 1996]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.636 was removed, effective January 1, 2006.

§ 417.638 Reopening determinations and decisions.

An organization, reconsidered, or revised determination made by an HMO, CMP, or CMS, or a decision or revised decision of an ALJ or the Departmental Appeals Board, may be reopened in accordance with the provisions of § 405.750 of this chapter.

[59 FR 59942, Nov. 21, 1994, as amended at 61 FR 32348, June 24, 1996]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.638 was removed, effective January 1, 2006.

Subpart R—Medicare Contract Appeals

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.640 Determinations subject to appeal.

This subpart establishes the procedures for making and reviewing the following initial determinations:

(a) A determination that an HMO or CMP is not qualified to enter into a contract with CMS under section 1876 of the Act.

(b) A determination that an HMO or CMP is qualified only for a reasonable cost contract.

(c) A determination to terminate, or to refuse to renew, a contract with an HMO or CMP because—

(1) The HMO or CMP has failed substantially to carry out the terms of the contract;

(2) The HMO or CMP is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of section 1876 of the Act;

(3) The HMO or CMP no longer meets the applicable conditions necessary to qualify as an HMO or CMP under section 1876 of the Act and this subpart; or

(4) The HMO or CMP has failed to comply with the composition of enrollment requirements specified in § 417.413(d).

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46572, Sept. 13, 1991; 58 FR 38080, July 15, 1993]

§ 417.642 Administrative actions that are not initial determinations.

Administrative actions that are not initial determinations under this subpart include, but are not limited to, CMS's refusal to renew a contract with an HMO or CMP when the refusal is not based on the causes specifed in § 417.640(c).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38080, July 15, 1993]

§417.644 Notice of initial determination.

(a) When CMS makes an initial determination, it gives the HMO or CMP written notice.

(b) The notice specifies—

(1) The reasons for the determination; and

(2) The HMO's or CMP's right to request reconsideration.

(c) CMS mails the notice to the HMO or CMP at least 90 days before the end of the contract period, or in the case of termination, at least 90 days before the effective date of the termination.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 60 FR 46234, Sept. 6, 1995]

§417.646 Effect of initial determination.

The initial determination is final and binding on all parties unless—

(a) It is reconsidered in accordance with §§417.648 through 417.658;

(b) In the case of an initial determination described in §417.640(c), a request for a hearing is filed; or

(c) It is revised as a result of a reopening under §417.692.

§417.648 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing an organization determination specified in §417.640(a) or (b).

(b) CMS reconsiders either of the specified determinations if the HMO or CMP files a written request in accordance with §417.650.

[60 FR 46234, Sept. 6, 1995]

§417.650 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* Except as provided in paragraph (c) of this section, the request for reconsideration must be filed within 60 days from the date of the notice of the initial determination.

(c) *Extension of time to file a request.* CMS may, in response to a party's written petition showing good cause, accept a request for reconsideration after the expiration of the 60 day period.

(d) *Proper party to file a request.* Only an authorized official of the entity that was a party to an initial determination may file the request for reconsideration.

(e) *Withdrawal of a request.* A request for reconsideration may be withdrawn by the party who filed the request at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS. If CMS approves, the request for reconsideration is withdrawn.

§417.652 Opportunity to submit evidence.

CMS provides the parties to the reconsideration reasonable opportunity to present as evidence any documents or written statements that are relevant and material to the matters at issue.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.654 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the initial determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the entity subsequent to the initial determination; and

(b) Affirms, reverses, or modifies the initial determination.

§417.656 Notice of reconsidered determination.

(a) CMS gives the parties written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings with respect to the HMO's or CMP's qualifications to enter into a contract with CMS under section 1876 of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the party of its right to a hearing if it is dissatisfied with the determination.

[60 FR 46234, Sept. 6, 1995]

§ 417.658 Effect of reconsidered determination.

A reconsidered determination is final and binding on all parties unless a request for a hearing is filed in accordance with § 417.662 or it is revised in accordance with § 417.692.

§ 417.660 Right to a hearing.

The following parties are entitled to a hearing:

(a) An entity that has been determined in a reconsidered determination to be unqualified to enter into a contract with CMS under section 1876 of the Act.

(b) An HMO or CMP that has been determined in a reconsidered determination to be qualified only for a reasonable cost contract.

(c) An HMO or CMP whose contract with CMS has been terminated or has not been renewed as a result of an initial determination as provided in § 417.640(c).

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993]

§ 417.662 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the entity or HMO or CMP that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* Except as provided in paragraph (c) of this section, a request for a hearing must be filed within 60 days after the date of receipt of the notice of initial or reconsidered determination.

(c) *Extension of time to file a request.* If good cause is shown, the 60-day period to request a hearing may be extended by CMS.

(d) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 417.660;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993]

§ 417.664 Postponement of effective date of initial determination.

When a request for a hearing with respect to an initial determination is filed timely—

(a) The effective date of the initial determination to terminate a contract with an HMO or CMP will be postponed until a hearing decision is reached; and

(b) The current contract will be extended at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract will be consistent with the purpose of section 1876 of the Act; and

(2) For such period as CMS and the HMO or CMP agree.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993]

§ 417.666 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.668 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted to CMS.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.670 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer will give the parties reasonable notice of any change in the time or place of hearing, or of adjournment or postponement.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993; 60 FR 46234, Sept. 6, 1995]

§417.672 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before CMS or otherwise prohibited by law.

§417.674 Authority of representatives.

(a) A representative appointed and qualified in accordance with §417.672 may, on behalf of the represented party—

(1) Give or accept any notice or request pertinent to the proceedings set forth in this subpart;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§417.676 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.678 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.680 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.682 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§417.684 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

§417.686 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision has been issued.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.688 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by CMS, and general instructions issued by CMS in implementing that Act.

§ 417.690 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reopened and revised in accordance with § 417.692.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.692 Reopening of initial or reconsidered determination or decision of a hearing officer.

(a) *Initial or reconsidered determination*. An initial or reconsidered determination may be reopened and revised by CMS upon its own motion within one year of the date of the notice of determination.

(b) *Decision of hearing officer*. A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within one year of the notice of the hearing decision. It may be reopened and revised by another hearing officer designated by CMS if the hearing officer who issued the decision is unavailable.

(c) *Notices*. (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

§ 417.694 Effect of revised determination.

The revision of an initial or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 417.662.

[50 FR 1346, Jan. 10, 1985, as amended at 60 FR 46234, Sept. 6, 1995]

Subparts S–T [Reserved]

Subpart U—Health Care Prepayment Plans

SOURCE: 50 FR 1375, Jan. 10, 1985, unless otherwise noted.

§ 417.800 Payment to HCPPs: Definitions and basic rules.

(a) *Definitions*. As used in this subpart, unless the context indicates otherwise—

Covered Part B services means physicians' services, diagnostic X-ray tests, laboratory, other diagnostic tests, and any additional medical and other health services, that the HCPP furnishes to its Medicare enrollees.

Health care prepayment plan (HCPP) means an organization that meets the following conditions:

(1) Effective January 1, 1999, (or on the effective date of the HCPP agreement in the case of a 1998 applicant) either—

(A) Is union or employer sponsored; or

(B) Does not provide, or arrange for the provision of, any inpatient hospital services.

(2) Is responsible for the organization, financing, and delivery of covered Part B services to a defined population on a prepayment basis.

(3) Meets the conditions specified in paragraph (b) of this section.

(4) Elects to be reimbursed on a reasonable cost basis.

Medicare enrollee means a beneficiary under Part B of Medicare who has been identified on CMS records as an enrollee of the HCPP. *Reporting period* means the period specified by CMS for which an HCPP must report its costs and utilization.

(b) *Qualifying conditions.* (1) Except as provided in paragraph (b)(2) of this section, an organization wishing to participate as an HCPP must—

(i) Enter into a written agreement with CMS as specified in §417.801;

(ii) Furnish physicians' services through its employees or under a formal arrangement with a medical group, independent practice association or individual physicians; and

(iii) Furnish covered Part B services to its Medicare enrollees through institutions, entities, and persons that have qualified under the applicable requirements of title XVIII of the Social Security Act and section 353 of the PHS Act.

(2) An organization that, as of January 31, 1983, was being reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act, and that would not otherwise meet the conditions specified in paragraph (b)(1) of this section, may receive reimbursement on a reasonable cost basis as an HCPP, provided it files an agreement with CMS as required by §417.801.

(c) *Payment of reasonable cost.* (1) Except as otherwise provided in this subpart, CMS pays an HCPP on the basis of the reasonable cost it incurs, as specified in subpart O of this part, for the covered Part B services furnished to its Medicare enrollees.

(2) *Payment for Part B services: Basic rules.* (i) *Cost basis payment.* Except as provided in paragraph (d) of this section, CMS pays an HCPP on the basis of the reasonable costs it incurs, as specified in subpart O of this part, for the covered Part B services furnished to its Medicare enrollees.

(ii) *Deductions.* In determining the amount due an HCPP for covered Part B services furnished to its Medicare enrollees, CMS deducts, from the reasonable cost actually incurred by the HCPP, the following:

(A) The actuarial value of the Part B deductible.

(B) An amount equal to 20 percent of the cost incurred for any service that is subject to the Medicare coinsurance.

(d) *Covered services not reimbursed to an HCPP.* (1) Services reimbursed under Part A are not reimbursable to an HCPP. CMS makes payment for these services directly to the hospital, or other provider of services, on a reasonable cost basis through the provider's Medicare fiscal intermediary (for more details, see parts 412 and 413 of this chapter).

(2) Covered Part B services furnished by a provider of services to an HCPP's Medicare enrollees are not payable to the HCPP. CMS makes payment for these services to the provider on behalf of the Medicare enrollee through the provider's Medicare fiscal intermediary. This requirement does not affect Medicare payment to the HCPP for physicians' services furnished to its Medicare enrollees for which the physicians are compensated by the HCPP.

(e) *Payment for services to nonenrollees.* CMS makes payment to an HCPP for covered Part B services furnished by the HCPP to a Medicare beneficiary who is not enrolled in the HCPP if the beneficiary assigns his rights to payment in accordance with §424.55 of this chapter. Payment is made on a reasonable charge basis through the HCPP's Medicare carrier.

[50 FR 1346, Jan. 10, 1985, as amended at 51 FR 34833, Sept. 30, 1986; 53 FR 6648, Mar. 2, 1988; 57 FR 7135, Feb. 28, 1992; 58 FR 38081, July 15, 1993; 60 FR 34888, July 5, 1995; 63 FR 35067, June 26, 1998; 63 FR 52611, Oct. 1, 1998]

§417.801 Agreements between CMS and health care prepayment plans.

(a) *General requirement.* (1) In order to participate and receive payment under the Medicare program as an HCPP as defined in §417.800, an organization must enter into a written agreement with CMS.

(2) An existing group practice prepayment plan (GPPP) that continues as an HCPP under this subpart U must have entered into a written agreement with CMS within 60 days of January 31, 1983.

(b) *Terms.* The agreement must provide that the HCPP agrees to—

(1) Maintain compliance with the requirements for participation and reimbursement on a reasonable cost basis of HCPPs as specified in §417.800;

(2) Not charge the Medicare enrollee or any other person for items or services for which that enrollee is entitled to have payment made under the provisions of this part, except for any deductible or coinsurance amounts for which the enrollee is liable;

(3) Refund, as promptly as possible, any money incorrectly collected as charges or premiums, or in any other way from Medicare enrollees in the HCPP in accordance with the requirements specified in § 417.456;

(4) Not impose any limitations on the acceptance of Medicare enrollees or beneficiaries for care and treatment that it does not impose on all other individuals;

(5) Meet the advance directives requirements specified in § 417.436(d) of this part;

(6) Establish administrative review procedures in accordance with §§ 417.830 through 417.840 for Medicare enrollees who are dissatisfied with denied services or claims; and

(7) Consider any additional requirements that CMS finds necessary or desirable for efficient and effective program administration.

(c) *Duration of agreement*. Except for the term of the initial agreement, the agreement is for a term of one year and may be renewed annually by mutual consent. The term of the initial agreement is set by CMS.

(d) *Termination or nonrenewal of agreement by CMS*. (1) CMS may terminate or not renew an agreement if it determines that—

(i) The HCPP no longer meets the requirements for participation and reimbursement as an HCPP as specified in § 417.800;

(ii) The HCPP is not in substantial compliance with the provisions of the agreement, applicable CMS regulations, or applicable provisions of the Medicare law; or

(iii) The HCPP undergoes a change in ownership as specified in subpart M of this part.

(2) CMS will give notice of termination or nonrenewal to the HCPP at least 90 days before the effective date stated in the notice.

(e) *Termination or nonrenewal of agreement by HCPP*. (1) If an HCPP does not wish to renew its agreement at the end of the term, it must give written notice to CMS at least 90 days before the end of the term of the agreement. If an HCPP wishes to terminate its agreement before the end of the term, it must file a written notice with CMS stating the intended effective date of termination.

(2) CMS may approve the termination date proposed by the HCPP, or set a different date no later than 6 months after that date. CMS makes this decision based on a finding that termination on a specific date would not—

(i) Unduly disrupt the furnishing of services to the community serviced by the HCPP; or

(ii) Otherwise interfere with the efficient administration of the Medicare program.

[50 FR 1375, Jan. 10, 1985, as amended at 57 FR 8202, Mar. 6, 1992; 58 FR 38081, July 15, 1993; 59 FR 49843, Sept. 30, 1994; 59 FR 59943, Nov. 21, 1994]

§ 417.802 Allowable costs.

(a) *General rule*. The costs that are considered allowable for HCPP reimbursement are the same as those for reasonable cost HMOs and CMPs specified in subpart O of this part, except those in §§ 417.531, 417.532 (a)(3) and (c) through (g), 417.536 (l) and (m), 417.546, 417.548, and 417.550(b)(2).

(b) *Physicians' services and other Part B supplier services furnished under arrangements*—(1) *Principle*. The amount paid by an HCPP for physicians' services and other Part B supplier services furnished under arrangements is an allowable cost to the extent it is reasonable.

(2) *Application: Payment on other than a fee-for-service basis*. If the HCPP pays for physicians' services and other Part B supplier services on other than a fee-for-service basis—

(i) Except as specified in paragraph (b)(2)(ii) of this section, the costs incurred by the HCPP may be considered reasonable if they—

(A) Do not exceed those that a prudent and cost-conscious buyer would incur to purchase those services; and

(B) Are comparable to costs incurred for similar services furnished by similar physicians and other suppliers in the same or a similar locality.

(ii)(A) If a physician group to whom the HCPP makes payment compensates its physicians on a fee-for-service basis, the HCPP's payment to the group may not exceed the reasonable charges for those services, as defined in subpart E of part 405 of this chapter.

(B) Payment in excess of the limits specified in paragraph (b)(2)(ii)(A) of this section is allowable if the group has procedures under which members of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In such cases, the amount paid by the HCPP is considered reasonable if it meets the conditions specified in paragraph (b)(2)(i) of this section.

(3) *Application: Payment on a fee-for-service basis.* If the HCPP pays for physicians' services and other Part B supplier services on a fee-for-service basis—

(i) Except as specified in paragraph (b)(3)(ii) of this section, the costs incurred by the HCPP are considered reasonable if they do not exceed—

(A) The reasonable charges for those services, as defined in subpart E of part 405 of this chapter; and

(B) The amount that CMS would pay for those services if they were furnished to beneficiaries who are not enrolled in the HCPP and who receive the services from sources other than providers of services or other entities that are reimbursed on a reasonable cost basis.

(ii) Payment to a physician group organized on an individual-practice basis is not subject to the paragraph (b)(3)(i) of this section if the group pays its physicians on a fee-for-service basis and has procedures under which the members of the group accept effective incentives, such as risk-sharing, designed to avoid unnecessary or unduly costly utilization of health services. In these cases, the amount paid by an HCPP is considered reasonable if it meets the conditions specified in paragraph (b)(2)(i) of this section.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993]

§ 417.804 Cost apportionment.

(a) The HCPP follows the cost apportionment principles specified in §§ 417.552 through 417.566, except for provisions on provider costs and provisions on departmental apportionment.

(b) The HCPP may use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

§ 417.806 Financial records, statistical data, and cost finding.

(a) The principles specified in § 417.568 apply to HCPPs, except those in paragraph (c) of that section.

(b) The HCPP may use a method for reporting costs that is approved by CMS. CMS bases its approval on a finding that the method—

(1) Results in an accurate and equitable allocation of allowable costs; and

(2) Is justifiable from an administrative and cost efficiency standpoint.

(c) An HCPP must permit the Department and the Comptroller General to audit or inspect any books and records of the HCPP and of any related organization that pertain to the determination of amounts payable for covered Part B services furnished its Medicare enrollees. For purposes of this requirement, the principles specified in § 417.486 apply to HCPPs.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993]

§ 417.808 Interim per capita payments.

The HCPP follows the principles specified in §§ 417.570 and 417.572 on interim per capita payments, except for the following:

(a) When applying these principles to HCPPs, the term ''reporting period'' should be used instead of the term ''contract period'' contained in that section.

(b) An HCPP must submit to CMS an annual operating budget and enrollment forecast, in the form and detail specified by CMS, at least 60 days before the beginning of each reporting period. A reporting period must be 12 consecutive months, except that the HCPP's initial reporting period for participating in Medicare may be as short as 6 months or as long as 18 months.

(c) An HCPP must submit to CMS an interim cost report and enrollment data applicable to the first 6-month period of the HCPP's reporting period in the form and detail specified by CMS. The interim cost report must be submitted not later than 45 days after the

close of the first 6-month period of the HCPP's reporting period.

(d) In lieu of an interim payment based on the actual monthly enrollment in an HCPP, CMS and the HCPP may agree to a uniform monthly interim reimbursement rate for a reporting period. This interim rate is based on the HCPP's budget and enrollment forecast, if CMS is satisfied that the rate is consistent with efficiency and economy, and will not result in excessive adjustment at the end of the reporting period.

§ 417.810 Final settlement.

(a) *General requirement.* CMS and an HCPP must make a final settlement, and payment of amounts due either to the HCPP or to CMS, following the submission and review of the HCPP's annual cost report and the supporting documents specified in paragraph (b) of this section.

(b) *Annual cost report as basis for final settlement*—(1) *Form and due date.* An HCPP must submit to CMS a cost report and supporting documents in the form and detail specified by CMS, no later than 120 days following the close of a reporting period.

(2) *Contents.* The report must include—

(i) The HCPP's per capita incurred costs of providing covered Part B services to its Medicare enrollees during the reporting period, including any costs incurred by another organization related to the HCPP by common ownership or control;

(ii) The HCPP's methods of apportioning costs among its Medicare enrollees, enrollees who are not Medicare beneficiaries, and other nonenrollees, including Medicare beneficiaries receiving health care services on a fee-for-service or other basis; and

(iii) Information on enrollment and other data as specified by CMS.

(3) *Extension of time to submit cost report.* CMS may grant an HCPP an extension of time to submit a cost report for good cause shown.

(4) *Failure to report required financial information.* If an HCPP does not submit the required cost report and supporting documents within the time specified in paragraph (b)(1) of this section, and has not requested and received an extension of time for good cause shown, CMS may—

(i) Regard the failure to report this information as evidence of likely overpayment and reduce or suspend interim payments to the HCPP; and

(ii) Determine that amounts previously paid are overpayments, and make appropriate recovery.

(c) *Determination of final settlement.* Following the HCPP's submission of the reports specified in paragraph (b) of this section in acceptable form, CMS makes a determination of the total reimbursement due the HCPP for the reporting period and the difference, if any, between this amount and the total interim payments made to the HCPP. CMS sends to the HCPP a notice of the amount of reimbursement by the Medicare program. This notice—

(1) Explains CMS's determination of total reimbursement due the HCPP for the reporting period; and

(2) Informs the HCPP of its right to have the determination reviewed at a hearing as provided in part 405, subpart R of this chapter.

(d) *Payment of amounts due.* (1) Within 30 days of CMS's determination, CMS or the HCPP, as appropriate, will make payment of any difference between the total amount due and the total interim payments made to the HCPP by CMS.

(2) If the HCPP does not pay CMS within 30 days of CMS's determination of any amounts the HCPP owes CMS, CMS may offset further payments to the HCPP to recover, or to aid in the recovery of, any overpayment identified in its determination.

(3) Any offset of payments CMS makes under paragraph (d)(2) of this section will remain in effect even if the HCPP has requested a hearing on the determination under the provisions of part 405, subpart R of this chapter.

(e) *Tentative settlement.* (1) If a final settlement cannot be made within 90 days after the HCPP submits the report specified in paragraph (b) of this section, CMS will make an interim settlement by estimating the amount payable to the HCPP.

(2) CMS or the HCPP will make payment within 30 days of CMS's determination under the tentative settlement of any estimated amounts due.

(3) The tentative settlement is subject to adjustment at the time of a final settlement.

[50 FR 1375, Jan. 10, 1985, as amended at 58 FR 38081, July 15, 1993]

§ 417.830 Scope of regulations on beneficiary appeals.

Sections 417.832 through 417.840 establish procedures for the presentation and resolution of organization determinations, reconsiderations, hearings, Departmental Appeals Board review, court reviews, and finality of decisions that are applicable to Medicare enrollees of an HCPP.

[59 FR 59943, Nov. 21, 1994, as amended at 61 FR 32348, June 24, 1996]

§ 417.832 Applicability of requirements and procedures.

(a) The administrative review rights and procedures specified in §§ 417.834 through 417.840 pertain to disputes involving an organization determination, as defined in § 417.838, with which the enrollee is dissatisfied.

(b) Physicians and other individuals who furnish items or services under arrangements with an HCPP have no right of administrative review under §§ 417.834 through 417.840.

(c) The provisions of part 405 dealing with the representation of parties apply to organization determinations and appeals.

[59 FR 59943, Nov. 21, 1994, as amended at 70 FR 4713, Jan. 28, 2005]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.832 was amended by adding paragraph (d), effective January 1, 2006. For the convenience of the user, the added text is set forth as follows:

§ 417.832 Applicability of requirements and procedures.

* * * * *

(d) The provisions of part 405 dealing with administrative law judge hearings, Medicare Appeals Council review, and judicial review are applicable, unless otherwise provided.

§ 417.834 Responsibility for establishing administrative review procedures.

The HCPP is responsible for establishing and maintaining the administrative review procedures that are specified in §§ 417.830 through 417.840.

[59 FR 59943, Nov. 21, 1994]

§ 417.836 Written description of administrative review procedures.

Each HCPP is responsible for ensuring that all Medicare enrollees are informed in writing of the administrative review procedures that are available to them.

[59 FR 59943, Nov. 21, 1994]

§ 417.838 Organization determinations.

(a) *Actions that are organization determinations.* For purposes of §§ 417.830 through 417.840, an organization determination is a refusal to furnish or arrange for services, or reimburse the party for services provided to the beneficiary, on the grounds that the services are not covered by Medicare.

(b) *Actions that are not organization determinations.* The following are not organization determinations for purposes of §§ 417.830 through 417.840:

(1) A determination regarding services that were furnished by the HCPP, either directly or under arrangement, for which the enrollee has no further obligation for payment.

(2) A determination regarding services that are not covered under the HCPP's agreement with CMS.

[59 FR 59943, Nov. 21, 1994]

§ 417.840 Administrative review procedures.

The HCPP must apply §§ 417.608 through 417.638 to organization determinations that affect its Medicare enrollees, and to reconsideration, hearings, Departmental Appeals Board review, and judicial review of those organization determinations.

[59 FR 59943, Nov. 21, 1994, as amended at 61 FR 32348, June 24, 1996]

EFFECTIVE DATE NOTE: At 70 FR 4713, Jan. 28, 2005, § 417.840 was revised, effective January 1, 2006. For the convenience of the user, the revised text is set forth as follows:

§ 417.840 Administrative review procedures.

The HCPP must apply § 422.568 through § 422.619 of this chapter to organization determinations that affect its Medicare enrollees, and to reconsiderations, hearings, Medicare

Appeals Council review, and judicial review of those organization determinations.

Subpart V—Administration of Outstanding Loans and Loan Guarantees

§ 417.910 Applicability.

The regulations in this subpart apply, as appropriate, to public and private entities that have loans or loan guarantees that—

(a) Were awarded to them before October 1986 under section 1304 or section 1305 of the PHS Act; and

(b) Are still outstanding.

[59 FR 49842, Sept. 30, 1994]

§ 417.911 Definitions.

As used in this subpart—

Any 12-month period means the 12-month period beginning on the first day of any month.

Expansion of services means—(1) The addition of any health service not previously provided by or through the HMO, that requires an increase in the facilities, equipment, or health professionals of the HMO; or

(2) The improvement or upgrading of existing facilities or equipment, or an increase in the number of categories of health professionals, of the HMO so that the HMO could provide directly services that it previously provided through contract or referral or which it could not previously provide with its existing facilities or equipment.

First 60 months of operation or expansion means the 60-month period beginning on the first day of the month during which the HMO first provided services to enrollees, or in the case of significant expansion, first provided services in accordance with its expansion plan.

Health system agency means an entity that has been designated in accordance with section 1515 of the PHS Act; and the term *State health planning and development agency* means an agency that has been designated in accordance with section 1521 of the PHS Act.

Initial costs of operation means any cost incurred in the first 60 months of an operation or expansion that met any of the following requirements:

(1) Under generally accepted accounting principles or under accounting practices prescribed or permitted by State regulatory authority, was not a capital cost.

(2) Was required by State regulatory authority to meet reserves or tangible net equity requirements.

(3) Was for a payment made to reduce balance sheet liabilities existing at the beginning of the 60-month period, but only if—(i) The payment had been approved in writing by the Secretary; and

(ii) The total of these payments did not exceed 20 percent of the amount of the loan.

(4) Was for a small capital expenditure, but only if—(i) The cost had been approved in writing by the Secretary; and

(ii) The total of these costs did not exceed $200,000 in any 12-month period, and $400,000 during the first 60 months of operation or expansion.

Nonprofit as applied to a private entity, means a private agency, institution, or organization, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

Significant expansion means—(1) A planned substantial increase in the enrollment of the HMO, that requires an increase in the number of health professionals serving enrollees of the HMO or an expansion of the physical capacity of the HMO's total health facilities; or

(2) A planned expansion of the service area beyond the current service area, that would be made possible by the addition of health service delivery facilities and health professionals to serve enrollees at a new site or sites in areas previously without service sites.

Small capital expenditure means expenditures for—(1) Equipment as defined in 45 CFR 74.132; or

(2) Alterations and renovations required to change the interior arrangements or other physical characteristics of an existing facility or installed equipment, so that it may be more effectively used for its currently designated purpose, or adapted to a changed use.

[58 FR 38076, July 15, 1993, as amended at 59 FR 49842, Sept. 30, 1994]

§ 417.920 Planning and initial development.

(a) Under section 1304 of the PHS Act, grants and loan guarantees were awarded for projects for planning and initial development of HMOs.

(b) Planning projects included projects for any of the following:

(1) Establishment of an HMO.

(2) Significant expansion of the HMO's enrollment or geographic area.

(c) Initial development projects included projects for any of the following:

(1) Establishment of an HMO.

(2) Significant expansion of the HMO's enrollment or geographic area.

(3) Expansion of the range or amount of services furnished by the HMO.

[58 FR 38076, July 15, 1993]

§ 417.930 Initial costs of operation.

Under section 1305 of the PHS, loans and loan guarantees were awarded for initial costs of operation of HMOs.

[58 FR 38077, July 15, 1993]

§ 417.931 [Reserved]

§ 417.934 Reserve requirement.

(a) *Timing*. Unless the Secretary approved a longer period, an entity that received a loan or loan guarantee under section 1305 of the PHS Act was required to establish a restricted reserve account on the earlier of the following:

(1) When the HMO's revenues and costs of operation reached the break-even point.

(2) At the end of the 60-month period following the Secretary's endorsement of the loan or loan guarantee.

(b) *Purpose and amount of reserve*. The reserve had to be constituted so as to accumulate, no later than 12 years after endorsement of the loan or loan guarantee, an amount equal to 1 year's principal and interest.

[59 FR 49842, Sept. 30, 1994]

§ 417.937 Loan and loan guarantee provisions.

(a) *Disbursement of loan proceeds*. The principal amount of any loan made or guaranteed by the Secretary under this subpart was disbursed to the entity in accordance with an agreement entered into between the parties to the loan and approved by the Secretary.

(b) *Length and maturity of loans*. The principal amount of each loan or loan guarantee, together with interest thereon, is repayable over a period of 22 years, beginning on the date of endorsement of the loan, or loan guarantee by the Secretary. The Secretary could approve a shorter repayment period if he or she determined that a repayment period of less than 22 years is more appropriate to an entity's total financial plan.

(c) *Repayment*. The principal amount of each loan or loan guarantee, together with interest thereon is repayable in accordance with a repayment schedule that is agreed upon by the parties to the loan or loan guarantee and approved by the Secretary before or at the time of endorsement of the loan. Unless otherwise specifically authorized by the Secretary, each loan made or guaranteed by the Secretary is repayable in substantially level combined installments of principal and interest to be paid at intervals not less frequently than annually, sufficient in amount to amortize the loan through the final year of the life of the loan. Principal repayment during the first 60 months of operation could be deferred with payment of interest only during that period. The Secretary could set rates of interest for each disbursement at a rate comparable to the rate of interest prevailing on the date of disbursement for marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

[59 FR 49842, Sept. 30, 1994]

§ 417.940 Civil action to enforce compliance with assurances.

The provisions of § 417.163(g) apply to entities that have outstanding loans or loan guarantees administered under this subpart.

[59 FR 49843, Sept. 30, 1994]

PART 418—HOSPICE CARE

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 48 FR 56026, Dec. 16, 1983, unless otherwise noted.

Subpart A—General Provision and Definitions

§ 418.1 Statutory basis.

This part implements section 1861(dd) of the Social Security Act. Section 1861(dd) specifies services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program. The following sections of the Act are also pertinent:

(a) Sections 1812(a) (4) and (d) of the Act specify eligibility requirements for the individual and the benefit periods.

(b) Section 1813(a)(4) of the Act specifies coinsurance amounts.

(c) Sections 1814(a)(7) and 1814(i) of the Act contain conditions and limitations on coverage of, and payment for, hospice care.

(d) Sections 1862(a) (1), (6) and (9) of the Act establish limits on hospice coverage.

[48 FR 56026, Dec. 16, 1983, as amended at 57 FR 36017, Aug. 12, 1992]

§ 418.2 Scope of part.

Subpart A of this part sets forth the statutory basis and scope and defines terms used in this part. Subpart B specifies the eligibility requirements and the benefit periods. Subpart C specifies conditions of participation for hospices. Subpart D describes the covered services and specifies the limits on services covered as hospice care. Subpart E specifies the reimbursement methods and procedures. Subpart F specifies coinsurance amounts applicable to hospice care.

§ 418.3 Definitions.

For purposes of this part—

Attending physician means a—(1)(i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or

(ii) Nurse practitioner who meets the training, education, and experience requirements as the Secretary may prescribe; and

(2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

Bereavement counseling means counseling services provided to the individual's family after the individual's death.

Cap period means the twelve-month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in § 418.309.

Employee means an employee (defined by section 210(j) of the Act) of the hospice or, if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice unit. ''Employee'' also refers to a volunteer under the jurisdiction of the hospice.

Hospice means a public agency or private organization or subdivision of either of these that—is primarily engaged in providing care to terminally ill individuals.

Physician means physician as defined in § 410.20 of this chapter.

Representative means an individual who has been authorized under State law to terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill individual who is mentally or physically incapacitated.

Social worker means a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education.

Terminally ill means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

[48 FR 56026, Dec. 16, 1983, as amended at 52 FR 4499, Feb. 12, 1987; 50 FR 50834, Dec. 11, 1990; 70 FR 45144, Aug. 4, 2005]

Subpart B—Eligibility, Election and Duration of Benefits

§ 418.20 Eligibility requirements.

In order to be eligible to elect hospice care under Medicare, an individual must be—

(a) Entitled to Part A of Medicare; and

(b) Certified as being terminally ill in accordance with § 418.22.

§ 418.21 Duration of hospice care coverage—Election periods.

(a) Subject to the conditions set forth in this part, an individual may elect to receive hospice care during one or more of the following election periods:

(1) An initial 90-day period.

(2) A subsequent 90-day period.

(3) A subsequent 30-day period.

(4) A subsequent extension period of unlimited duration during the individual's lifetime.

(b) The periods of care are available in the order listed and may be elected separately at different times.

[55 FR 50834, Dec. 11, 1990, as amended at 57 FR 36017, Aug. 12, 1992]

§ 418.22 Certification of terminal illness.

(a) *Timing of certification*—(1) *General rule*. The hospice must obtain written certification of terminal illness for each of the periods listed in § 418.21, even if a single election continues in effect for two, three, or four periods, as provided in § 418.24(c).

(2) *Basic requirement*. Except as provided in paragraph (a)(3) of this section, the hospice must obtain the written certification no later than two calendar days after the period begins.

(3) *Exception*. For the initial 90-day period, if the hospice cannot obtain the written certifications within two calendar days, it must obtain oral certifications within two calendar days, and written certifications no later than eight calendar days after the period begins.

(b) *Content of certification*. The certification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course.

(c) *Sources of certification*. (1) For the initial 90-day period, the hospice must obtain written certification statements (and oral certification statements if required under paragraph (a)(3) of this section) from—

(i) The medical director of the hospice or the physician member of the hospice interdisciplinary group; and

(ii) The individual's attending physician, if the individual has an attending physician. The attending physician must meet the definition of physician specified in § 410.20 of this subchapter.

(2) For subsequent periods, the only requirement is certification by one of the physicians listed in paragraph (c)(1)(i) of this section.

(d) *Maintenance of records*. Hospice staff must—

(1) Make an appropriate entry in the patient's medical record as soon as they receive an oral certification; and

(2) File written certifications in the medical record.

[55 FR 50834, Dec. 11, 1990, as amended at 57 FR 36017, Aug. 12, 1992; 70 FR 45144, Aug. 4, 2005]

§ 418.24 Election of hospice care.

(a) *Filing an election statement*. An individual who meets the eligibility requirement of § 418.20 may file an election statement with a particular hospice. If the individual is physically or mentally incapacitated, his or her representative (as defined in § 418.3) may file the election statement.

(b) *Content of election statement*. The election statement must include the following:

(1) Identification of the particular hospice that will provide care to the individual.

(2) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(3) Acknowledgement that certain Medicare services, as set forth in paragraph (d) of this section, are waived by the election.

(4) The effective date of the election, which may be the first day of hospice care or a later date, but may be no earlier than the date of the election statement.

(5) The signature of the individual or representative.

(c) *Duration of election*. An election to receive hospice care will be considered to continue through the initial election period and through the subsequent election periods without a break in care as long as the individual—

(1) Remains in the care of a hospice; and

(2) Does not revoke the election under the provisions of § 418.28.

(d) *Waiver of other benefits*. For the duration of an election of hospice care, an individual waives all rights to Medicare payments for the following services:

(1) Hospice care provided by a hospice other than the hospice designated by the individual (unless provided under arrangements made by the designated hospice).

(2) Any Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition or that are equivalent to hospice care except for services—

(i) Provided by the designated hospice:

(ii) Provided by another hospice under arrangements made by the designated hospice; and

(iii) Provided by the individual's attending physician if that physician is not an employee of the designated hospice or receiving compensation from the hospice for those services.

(e) *Re-election of hospice benefits*. If an election has been revoked in accordance with § 418.28, the individual (or his or her representative if the individual is mentally or physically incapacitated) may at any time file an election, in accordance with this section, for any other election period that is still available to the individual.

[55 FR 50834, Dec. 11, 1990]

§ 418.28 Revoking the election of hospice care.

(a) An individual or representative may revoke the individual's election of hospice care at any time during an election period.

(b) To revoke the election of hospice care, the individual or representative must file a statement with the hospice that includes the following information:

(1) A signed statement that the individual or representative revokes the individual's election for Medicare coverage of hospice care for the remainder of that election period.

(2) The date that the revocation is to be effective. (An individual or representative may not designate an effective date earlier than the date that the revocation is made).

(c) An individual, upon revocation of the election of Medicare coverage of hospice care for a particular election period—

(1) Is no longer covered under Medicare for hospice care;

(2) Resumes Medicare coverage of the benefits waived under § 418.24(e)(2); and

(3) May at any time elect to receive hospice coverage for any other hospice election periods that he or she is eligible to receive.

§ 418.30 Change of the designated hospice.

(a) An individual or representative may change, once in each election period, the designation of the particular hospice from which hospice care will be received.

(b) The change of the designated hospice is not a revocation of the election for the period in which it is made.

(c) To change the designation of hospice programs, the individual or representative must file, with the hospice from which care has been received and with the newly designated hospice, a statement that includes the following information:

(1) The name of the hospice from which the individual has received care and the name of the hospice from which he or she plans to receive care.

(2) The date the change is to be effective.

Subpart C—Conditions of Participation—General Provisions and Administration

§ 418.50 Condition of participation—General provisions.

(a) *Standard: Compliance*. A hospice must maintain compliance with the conditions of this subpart and subparts D and E of this part.

(b) *Standard: Required services*. A hospice must be primarily engaged in providing the care and services described in § 418.202, must provide bereavement counseling and must—

(1) Make nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis;

(2) Make all other covered services available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness and related conditions; and

(3) Provide these services in a manner consistent with accepted standards of practice.

(c) *Standard: Disclosure of information*. The hospice must meet the disclosure

of information requirements at § 420.206 of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50834, Dec. 11, 1990]

§ 418.52 Condition of participation—Governing body.

A hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospice's total operation. The governing body must designate an individual who is responsible for the day to day management of the hospice program. The governing body must also ensure that all services provided are consistent with accepted standards of practice.

§ 418.54 Condition of participation—Medical director.

The medical director must be a hospice employee who is a doctor of medicine or osteopathy who assumes overall responsibility for the medical component of the hospice's patient care program.

§ 418.56 Condition of participation—Professional management.

Subject to the conditions of participation pertaining to services in §§ 418.80 and 418.90, a hospice may arrange for another individual or entity to furnish services to the hospice's patients. If services are provided under arrangement, the hospice must meet the following standards:

(a) *Standard: Continuity of care.* The hospice program assures the continuity of patient/family care in home, outpatient, and inpatient settings.

(b) *Standard: Written agreement.* The hospice has a legally binding written agreement for the provision of arranged services. The agreement includes at least the following:

(1) Identification of the services to be provided.

(2) A stipulation that services may be provided only with the express authorization of the hospice.

(3) The manner in which the contracted services are coordinated, supervised, and evaluated by the hospice.

(4) The delineation of the role(s) of the hospice and the contractor in the admission process, patient/family assessment, and the interdisciplinary group care conferences.

(5) Requirements for documenting that services are furnished in accordance with the agreement.

(6) The qualifications of the personnel providing the services.

(c) *Standard: Professional management responsibility.* The hospice retains professional management responsibility for those services and ensures that they are furnished in a safe and effective manner by persons meeting the qualifications of this part, and in accordance with the patient's plan of care and the other requirements of this part.

(d) *Standard: Financial responsibility.* The hospice retains responsibility for payment for services.

(e) *Standard: Inpatient care.* The hospice ensures that inpatient care is furnished only in a facility which meets the requirements in § 418.98 and its arrangement for inpatient care is described in a legally binding written agreement that meets the requirements of paragraph (b) and that also specifies, at a minimum—

(1) That the hospice furnishes to the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

(2) That the inpatient provider has established policies consistent with those of the hospice and agrees to abide by the patient care protocols established by the hospice for its patients;

(3) That the medical record includes a record of all inpatient services and events and that a copy of the discharge summary and, if requested, a copy of the medical record are provided to the hospice;

(4) The party responsible for the implementation of the provisions of the agreement; and

(5) That the hospice retains responsibility for appropriate hospice care training of the personnel who provide the care under the agreement.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983]

§ 418.58 Condition of participation—Plan of care.

A written plan of care must be established and maintained for each individual admitted to a hospice program,

and the care provided to an individual must be in accordance with the plan.

(a) *Standard: Establishment of plan.* The plan must be established by the attending physician, the medical director or physician designee and interdisciplinary group prior to providing care.

(b) *Standard: Review of plan.* The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, the medical director or physician designee and interdisciplinary group. These reviews must be documented.

(c) *Standard: Content of plan.* The plan must include an assessment of the individual's needs and identification of the services including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

§ 418.60 Condition of participation—Continuation of care.

A hospice may not discontinue or diminish care provided to a Medicare beneficiary because of the beneficiary's inability to pay for that care.

§ 418.62 Condition of participation—Informed consent.

A hospice must demonstrate respect for an individual's rights by ensuring that an informed consent form that specifies the type of care and services that may be provided as hospice care during the course of the illness has been obtained for every individual, either from the individual or representative as defined in § 418.3.

§ 418.64 Condition of participation—Inservice training.

A hospice must provide an ongoing program for the training of its employees.

§ 418.66 Condition of participation—Quality assurance.

A hospice must conduct an ongoing, comprehensive, integrated, self-assessment of the quality and appropriateness of care provided, including inpatient care, home care and care provided under arrangements. The findings are used by the hospice to correct identified problems and to revise hospice policies if necessary. Those responsible for the quality assurance program must—

(a) Implement and report on activities and mechanisms for monitoring the quality of patient care;

(b) Identify and resolve problems; and

(c) Make suggestions for improving patient care.

§ 418.68 Condition of participation—Interdisciplinary group.

The hospice must designate an interdisciplinary group or groups composed of individuals who provide or supervise the care and services offered by the hospice.

(a) *Standard: Composition of group.* The hospice must have an interdisciplinary group or groups that include at least the following individuals who are employees of the hospice:

(1) A doctor of medicine or osteopathy.

(2) A registered nurse.

(3) A social worker.

(4) A pastoral or other counselor.

(b) *Standard: Role of group.* The interdisciplinary group is responsible for—

(1) Participation in the establishment of the plan of care;

(2) Provision or supervision of hospice care and services;

(3) Periodic review and updating of the plan of care for each individual receiving hospice care; and

(4) Establishment of policies governing the day-to-day provision of hospice care and services.

(c) If a hospice has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in paragraph (b)(4) of this section.

(d) *Standard: Coordinator.* The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.

§ 418.70 Condition of participation—Volunteers.

The hospice in accordance with the numerical standards, specified in paragraph (e) of this section, uses volunteers, in defined roles, under the supervision of a designated hospice employee.

(a) *Standard: Training.* The hospice must provide appropriate orientation

and training that is consistent with acceptable standards of hospice practice.

(b) *Standard: Role.* Volunteers must be used in administrative or direct patient care roles.

(c) *Standard: Recruiting and retaining.* The hospice must document active and ongoing efforts to recruit and retain volunteers.

(d) *Standard: Cost saving.* The hospice must document the cost savings achieved through the use of volunteers. Documentation must include—

(1) The identification of necessary positions which are occupied by volunteers;

(2) The work time spent by volunteers occupying those positions; and

(3) Estimates of the dollar costs which the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) for the amount of time specified in paragraph (d)(2).

(e) *Standard: Level of activity.* A hospice must document and maintain a volunteer staff sufficient to provide administrative or direct patient care in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. The hospice must document a continuing level of volunteer activity. Expansion of care and services achieved through the use of volunteers, including the type of services and the time worked, must be recorded.

(f) *Standard: Availability of clergy.* The hospice must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request such visits and must advise patients of this opportunity.

§ 418.72 Condition of participation—Licensure.

The hospice and all hospice employees must be licensed in accordance with applicable Federal, State and local laws and regulations.

(a) *Standard: Licensure of program.* If State or local law provides for licensing of hospices, the hospice must be licensed.

(b) *Standard: Licensure of employees.* Employees who provide services must be licensed, certified or registered in accordance with applicable Federal or State laws.

§ 418.74 Condition of participation—Central clinical records.

In accordance with accepted principles of practice, the hospice must establish and maintain a clinical record for every individual receiving care and services. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval.

(a) *Standard: Content.* Each clinical record is a comprehensive compilation of information. Entries are made for all services provided. Entries are made and signed by the person providing the services. The record includes all services whether furnished directly or under arrangements made by the hospice. Each individual's record contains—

(1) The initial and subsequent assessments;

(2) The plan of care;

(3) Identification data;

(4) Consent and authorization and election forms;

(5) Pertinent medical history; and

(6) Complete documentation of all services and events (including evaluations, treatments, progress notes, etc.).

(b) *Standard; Protection of information.* The hospice must safeguard the clinical record against loss, destruction and unauthorized use.

Subpart D—Conditions of Participation: Core Services

§ 418.80 Condition of participation—Furnishing of core services.

Except as permitted in § 418.83, a hospice must ensure that substantially all the core services described in this subpart are routinely provided directly by hospice employees. A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the

qualifications of staff and services provided meet the requirements specified in this subpart.

[52 FR 7416, Mar. 11, 1987, as amended at 55 FR 50835, Dec. 11, 1990]

§ 418.82 Condition of participation—Nursing services.

The hospice must provide nursing care and services by or under the supervision of a registered nurse.

(a) Nursing services must be directed and staffed to assure that the nursing needs of patients are met.

(b) Patient care responsibilities of nursing personnel must be specified.

(c) Services must be provided in accordance with recognized standards of practice.

§ 418.83 Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.

(a) CMS may approve a waiver of the requirement in § 418.80 for nursing services provided by a hospice which is located in a non-urbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence that it was operational on or before January 1, 1983, and that it made a good faith effort to hire a sufficient number of nurses to provide services directly. CMS bases its decision as to whether to approve a waiver application on the following:

(1) The current Bureau of the Census designations for determining non-urbanized areas.

(2) Evidence that a hospice was operational on or before January 1, 1983 including:

(i) Proof that the organization was established to provide hospice services on or before January 1, 1983;

(ii) Evidence that hospice-type services were furnished to patients on or before January 1, 1983; and

(iii) Evidence that the hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983.

(3) Evidence that a hospice made a good faith effort to hire nurses, including:

(i) Copies of advertisements in local newspapers that demonstrate recruitment efforts;

(ii) Job descriptions for nurse employees;

(iii) Evidence that salary and benefits are competitive for the area; and

(iv) Evidence of any other recruiting activities (e.g., recruiting efforts at health fairs and contacts with nurses at other providers in the area);

(b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received.

(c) Waivers will remain effective for one year at a time.

(d) CMS may approve a maximum of two one-year extensions for each initial waiver. If a hospice wishes to receive a one-year extension, the hospice must submit a certification to CMS, prior to the expiration of the waiver period, that the employment market for nurses has not changed significantly since the time the initial waiver was granted.

[52 FR 7416, Mar. 11, 1987]

§ 418.84 Condition of participation—Medical social services.

Medical social services must be provided by a qualified social worker, under the direction of a physician.

§ 418.86 Condition of participation—Physician services.

In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice, including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician.

§ 418.88 Condition of participation—Counseling services.

Counseling services must be available to both the individual and the family. Counseling includes bereavement counseling, provided after the patient's death as well as dietary, spiritual and any other counseling services for the individual and family provided while the individual is enrolled in the hospice.

(a) *Standard: Bereavement counseling.* There must be an organized program

for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, as well as a clear delineation of services to be provided and the frequency of service delivery (up to one year following the death of the patient). A special coverage provision for bereavement counseling is specified § 418.204(c).

(b) *Standard: Dietary counseling.* Dietary counseling, when required, must be provided by a qualified individual.

(c) *Standard: Spiritual counseling.* Spiritual counseling must include notice to patients as to the availability of clergy as provided in § 418.70(f).

(d) *Standard: Additional counseling.* Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the hospice.

Subpart E—Conditions of Participation: Other Services

§ 418.90 Condition of participation—Furnishing of other services.

A hospice must ensure that the services described in this subpart are provided directly by hospice employees or under arrangements made by the hospice as specified in § 418.56.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

§ 418.92 Condition of participation—Physical therapy, occupational therapy, and speech-language pathology.

(a) Physical therapy services, occupational therapy services, and speech-language patholgy services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

(b)(1) If the hospice engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the hospice chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

[57 FR 7135, Feb. 28, 1992]

§ 418.94 Condition of participation—Home health aide and homemaker services.

Home health aide and homemaker services must be available and adequate in frequency to meet the needs of the patients. A home health aide is a person who meets the training, attitude and skill requirements specified in § 484.36 of this chapter.

(a) *Standard: Supervision.* A registered nurse must visit the home site at least every two weeks when aide services are being provided, and the visit must include an assessment of the aide services.

(b) *Standard: Duties.* Written instructions for patient care are prepared by a registered nurse. Duties include, but may not be limited to, the duties specified in § 484.36(c) of this chapter.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

§ 418.96 Condition of participation—Medical supplies.

Medical supplies and appliances including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness and related conditions.

(a) *Standard: Administration.* All drugs and biologicals must be administered in accordance with accepted standards of practice.

(b) *Standard: Controlled drugs in the patient's home.* The hospice must have a policy for the disposal of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.

(c) *Standard: Administration of drugs and biologicals.* Drugs and biologicals are administered only by the following individuals:

(1) A licensed nurse or physician.

(2) An employee who has completed a State-approved training program in medication administration.

(3) The patient if his or her attending physician has approved.

(4) Any other individual in accordance with applicable State and local

laws. The persons, and each drug and biological they are authorized to administer, must be specified in the patient's plan of care.

§418.98 Condition of participation—Short term inpatient care.

Inpatient care must be available for pain control, symptom management and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

(a) *Standard: Inpatient care for symptom control.* Inpatient care for pain control and symptom management must be provided in one of the following:

(1) A hospice that meets the condition of participation for providing inpatient care directly as specified in §418.100.

(2) A hospital or an SNF that also meets the standards specified in §418.100 (a) and (e) regarding 24-hour nursing service and patient areas.

(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) An ICF that also meets the standards specified in §418.100 (a) and (e) regarding 24-hour nursing service and patient areas.

(c) *Standard: Inpatient care limitation.* The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in any 12-month period preceding a certification survey in a particular hospice may not exceed 20 percent of the total number of hospice days for this group of beneficiaries.

(d) *Standard: Exemption from limitation.* Until October 1, 1986, any hospice that began operation before January 1, 1975 is not subject to the limitation specified in paragraph (c).

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

§418.100 Condition of participation Hospices that provide inpatient care directly.

A hospice that provides inpatient care directly must comply with all of the following standards.

(a) *Standard: Twenty-four-hour nursing services.* (1) The facility provides 24-hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient plan of care. Each patient receives treatments, medications, and diet as prescribed, and is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) Each shift must include a registered nurse who provides direct patient care.

(b) *Standard: Disaster preparedness.* The hospice has an acceptable written plan, periodically rehearsed with staff, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from such disasters.

(c) *Standard: Health and safety laws.* The hospice must meet all Federal, State, and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating—

(1) Construction, maintenance, and equipment for the hospice;

(2) Sanitation;

(3) Communicable and reportable diseases; and

(4) Post mortem procedures.

(d) *Standard: Fire protection.* (1) Except as otherwise provided in this section—

(i) The hospice must meet the provisions applicable to nursing homes of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in

this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to a hospice.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of the patients.

(3) The provisions of the adopted edition of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in hospices.

(4) Beginning March 13, 2006, a hospice must be in compliance with Chapter 9.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospices.

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospice may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(e) *Standard: Patient areas.* (1) The hospice must design and equip areas for the comfort and privacy of each patient and family members.

(2) The hospice must have—

(i) Physical space for private patient/family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night;

(iii) Accommodations for family privacy after a patient's death; and

(iv) Decor which is homelike in design and function.

(3) Patients must be permitted to receive visitors at any hour, including small children.

(f) *Standard: Patient rooms and toilet facilities.* Patient rooms are designed and equipped for adequate nursing care and the comfort and privacy of patients.

(1) Each patient's room must—

(i) Be equipped with or conveniently located near toilet and bathing facilities;

(ii) Be at or above grade level;

(iii) Contain a suitable bed for each patient and other appropriate furniture;

(iv) Have closet space that provides security and privacy for clothing and personal belongings;

(v) Contain no more than four beds;

(vi) Measure at least 100 square feet for a single patient room or 80 square feet for each patient for a multipatient room; and

(vii) Be equipped with a device for calling the staff member on duty.

(2) For an existing building, CMS may waive the space and occupancy requirements of paragraphs (f)(1) (v) and (vi) of this section for as long as it is considered appropriate if it finds that—

(i) The requirements would result in unreasonable hardship on the hospice if strictly enforced; and

(ii) The waiver serves the particular needs of the patients and does not adversely affect their health and safety.

(g) *Standard: Bathroom facilities.* The hospice must—

(1) Provide an adequate supply of hot water at all times for patient use; and

(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(h) *Standard: Linen.* The hospice has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(i) *Standard: Isolation areas.* The hospice must make provision for isolating patients with infectious diseases.

(j) *Standard: Meal service, menu planning, and supervision.* The hospice must—

(1) Serve at least three meals or their equivalent each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast;

(2) Procure, store, prepare, distribute, and serve all food under sanitary conditions;

(3) Have a staff member trained or experienced in food management or nutrition who is responsible for—

(i) Planning menus that meet the nutritional needs of each patient, following the orders of the patient's physician and, to the extent medically possible, the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances (9th ed., 1981) is available from the Printing and Publications Office, National Academy of Sciences, Washington, DC 20418); and

(ii) Supervising the meal preparation and service to ensure that the menu plan is followed; and

(4) If the hospice has patients who require medically prescribed special diets, have the menus for those patients planned by a professionally qualified dietitian and supervise the preparation and serving of meals to ensure that the patient accepts the special diet.

(k) *Standard: Pharmaceutical services.* The hospice provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacists or stocked by the facility, the facility is responsible for drugs and biologicals for its patients, insofar as they are covered under the program and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate Federal, State, and local laws. (See §405.1124(g), (h), and (i) of this chapter.)

(1) *Licensed pharmacist.* The hospice must—

(i) Employ a licensed pharmacist; or

(ii) Have a formal agreement with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.

(2) *Orders for medications.* (i) A physician must order all medications for the patient.

(ii) If the medication order is verbal—

(A) The physician must give it only to a licensed nurse, pharmacist, or another physician; and

(B) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in a manner consistent with good medical practice.

(3) *Administering medications.* Medications are administered only by one of the following individuals:

(i) A licensed nurse or physician.

(ii) An employee who has completed a State-approved training program in medication administration.

(iii) The patient if his or her attending physician has approved.

(4) *Control and accountability.* The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility. Drugs are dispensed in compliance with Federal and State laws. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation. The pharmacist determines that drug records are in order

and that an account of all controlled drugs is maintained and reconciled.

(5) *Labeling of drugs and biologicals.* The labeling of drugs and biologicals is based on currently accepted professional principles, and includes the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.

(6) *Storage.* In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls and only authorized personnel have access to the keys. Separately locked compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. An emergency medication kit is kept readily available.

(7) *Drug disposal.* Controlled drugs no longer needed by the patient are disposed of in compliance with State requirements. In the absence of State requirements, the pharmacist and a registered nurse dispose of the drugs and prepare a record of the disposal.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983; 49 FR 23010, June 1, 1984, as amended at 53 FR 11509, Apr. 7, 1988; 55 FR 50835, Dec. 11, 1990; 68 FR 1386, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 69 FR 49266, Aug. 11, 2004; 70 FR 15237, Mar. 25, 2005]

Subpart F—Covered Services

§ 418.200 Requirements for coverage.

To be covered, hospice services must meet the following requirements. They must be reasonable and necessary for the palliation or management of the terminal illness as well as related conditions. The individual must elect hospice care in accordance with § 418.24 and a plan of care must be established as set forth in § 418.58 before services are provided. The services must be consistent with the plan of care. A certification that the individual is terminally ill must be completed as set forth in § 418.22.

§ 418.202 Covered services.

All services must be performed by appropriately qualified personnel, but it is the nature of the service, rather than the qualification of the person who provides it, that determines the coverage category of the service. The following services are covered hospice services:

(a) Nursing care provided by or under the supervision of a registered nurse.

(b) Medical social services provided by a social worker under the direction of a physician.

(c) Physicians' services performed by a physician as defined in § 410.20 of this chapter except that the services of the hospice medical director or the physician member of the interdisciplinary group must be performed by a doctor of medicine or osteopathy.

(d) Counseling services provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other caregiver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death.

(e) Short-term inpatient care provided in a participating hospice inpatient unit, or a participating hospital or SNF, that additionally meets the standards in § 418.202 (a) and (e) regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management.

Inpatient care may also be furnished as a means of providing respite for the individual's family or other persons caring for the individual at home. Respite care must be furnished as specified in § 418.98(b). Payment for inpatient care will be made at the rate appropriate to the level of care as specified in § 418.302.

(f) Medical appliances and supplies, including drugs and biologicals. Only drugs as defined in section 1861(t) of the Act and which are used primarily

for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment as described in § 410.38 of this chapter as well as other self-help and personal comfort items related to the palliation or management of the patient's terminal illness. Equipment is provided by the hospice for use in the patient's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care.

(g) *Home health aide services furnished by qualified aides as designated in § 418.94 and homemaker services.* Home health aides may provide personal care services as defined in § 409.45(b) of this chapter. Aides may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing bed linens or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.

(h) Physical therapy, occupational therapy and speech-language pathology services in addition to the services described in § 409.33 (b) and (c) of this chapter provided for purposes of symptom control or to enable the patient to maintain activities of daily living and basic functional skills.

[48 FR 56026, Dec. 16, 1983, as amended at 51 FR 41351, Nov. 14, 1986; 55 FR 50835, Dec. 11, 1990; 59 FR 65498, Dec. 20, 1994]

§ 418.204 Special coverage requirements.

(a) *Periods of crisis.* Nursing care may be covered on a continuous basis for as much as 24 hours a day during periods of crisis as necessary to maintain an individual at home. Either homemaker or home health aide services or both may be covered on a 24-hour continuous basis during periods of crisis but care during these periods must be predominantly nursing care. A period of crisis is a period in which the individual requires continuous care to achieve palliation or management of acute medical symptoms.

(b) *Respite care.* (1) Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual.

(2) Respite care may be provided only on an occasional basis and may not be reimbursed for more than five consecutive days at a time.

(c) *Bereavement counseling.* Bereavement counseling is a required hospice service but it is not reimbursable.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

§ 418.205 Special requirements for hospice pre-election evaluation and counseling services.

(a) *Definition.* As used in this section the following definition applies.

Terminal illness has the same meaning as defined in § 418.3.

(b) *General.* Effective January 1, 2005, payment for hospice pre-election evaluation and counseling services as specified in §418.304(d) may be made to a hospice on behalf of a Medicare beneficiary if the requirements of this section are met.

(1) *The beneficiary.* The beneficiary:

(i) Has been diagnosed as having a terminal illness as defined in § 418.3.

(ii) Has not made a hospice election.

(iii) Has not previously received hospice pre-election evaluation and consultation services specified under this section.

(2) *Services provided.* The hospice pre-election services include an evaluation of an individual's need for pain and symptom management and counseling regarding hospice and other care options. In addition, the services may include advising the individual regarding advanced care planning.

(3) *Provision of pre-election hospice services.*

(i) The services must be furnished by a physician.

(ii) The physician furnishing these services must be an employee or medical director of the hospice billing for this service.

(iii) The services cannot be furnished by hospice personnel other than employed physicians, such as but not limited to nurse practitioners, nurses, or

social workers, physicians under contractual arrangements with the hospice or by the beneficiary's physician, if that physician is not an employee of the hospice.

(iv) If the beneficiary's attending physician is also the medical director or a physician employee of the hospice, the attending physician may not provide nor may the hospice bill for this service because that physician already possesses the expertise necessary to furnish end-of-life evaluation and management, and counseling services.

(4) *Documentation.* (i) If the individual's physician initiates the request for services of the hospice medical director or physician, appropriate documentation is required.

(ii) The request or referral must be in writing, and the hospice medical director or physician employee is expected to provide a written note on the patient's medical record.

(iii) The hospice agency employing the physician providing these services is required to maintain a written record of the services furnished.

(iv) If the services are initiated by the beneficiary, the hospice agency is required to maintain a record of the services and documentation that communication between the hospice medical director or physician and the beneficiary's physician occurs, with the beneficiary's permission, to the extent necessary to ensure continuity of care.

[69 FR 66425, Nov. 15, 2004]

Subpart G—Payment for Hospice Care

§ 418.301 Basic rules.

(a) Medicare payment for covered hospice care is made in accordance with the method set forth in § 418.302.

(b) Medicare reimbursement to a hospice in a cap period is limited to a cap amount specified in § 418.309.

[48 FR 56026, Dec. 16, 1983, as amended at 56 FR 26919, June 12, 1991]

§ 418.302 Payment procedures for hospice care.

(a) CMS establishes payment amounts for specific categories of covered hospice care.

(b) Payment amounts are determined within each of the following categories:

(1) *Routine home care day.* A routine home care day is a day on which an individual who has elected to receive hospice care is at home and is not receiving continuous care as defined in paragraph (b)(2) of this section.

(2) *Continuous home care day.* A continuous home care day is a day on which an individual who has elected to receive hospice care is not in an inpatient facility and receives hospice care consisting predominantly of nursing care on a continuous basis at home. Home health aide or homemaker services or both may also be provided on a continuous basis. Continuous home care is only furnished during brief periods of crisis as described in § 418.204(a) and only as necessary to maintain the terminally ill patient at home.

(3) *Inpatient respite care day.* An inpatient respite care day is a day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite.

(4) *General inpatient care day.* A general inpatient care day is a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings.

(c) The payment amounts for the categories of hospice care are fixed payment rates that are established by CMS in accordance with the procedures described in § 418.306. Payment rates are determined for the following categories:

(1) Routine home care.

(2) Continuous home care.

(3) Inpatient respite care.

(4) General inpatient care.

(d)(1) The intermediary reimburses the hospice its appropriate payment amount for each day for which an eligible Medicare beneficiary is under the hospice's care.

(2) Effective December 8, 2003, if a hospice makes arrangements with another hospice to provide services under the circumstances specified in section 1861(dd)(5)(D) of the Act, the intermediary reimburses the hospice for which the beneficiary has made an

election as described in paragraph (d)(1) of this section.

(e) The intermediary makes payment according to the following procedures:

(1) Payment is made to the hospice for each day during which the beneficiary is eligible and under the care of the hospice, regardless of the amount of services furnished on any given day.

(2) Payment is made for only one of the categories of hospice care described in §418.302(b) for any particular day.

(3) On any day on which the beneficiary is not an inpatient, the hospice is paid the routine home care rate, unless the patient receives continuous care as defined in paragraph (b)(2) of this section for a period of at least 8 hours. In that case, a portion of the continuous care day rate is paid in accordance with paragraph (e)(4) of this section.

(4) The hospice payment on a continuous care day varies depending on the number of hours of continuous services provided. The continuous home care rate is divided by 24 to yield an hourly rate. The number of hours of continuous care provided during a continuous home care day is then multiplied by the hourly rate to yield the continuous home care payment for that day. A minimum of 8 hours of care must be furnished on a particular day to qualify for the continuous home care rate.

(5) Subject to the limitations described in paragraph (f) of this section, on any day on which the beneficiary is an inpatient in an approved facility for inpatient care, the appropriate inpatient rate (general or respite) is paid depending on the category of care furnished. The inpatient rate (general or respite) is paid for the date of admission and all subsequent inpatient days, except the day on which the patient is discharged. For the day of discharge, the appropriate home care rate is paid unless the patient dies as an inpatient. In the case where the beneficiary is discharged deceased, the inpatient rate (general or respite) is paid for the discharge day. Payment for inpatient respite care is subject to the requirement that it may not be provided consecutively for more than 5 days at a time. Payment for the sixth and any subsequent day of respite care is made at the routine home care rate.

(f) Payment for inpatient care is limited as follows: (1) The total payment to the hospice for inpatient care (general or respite) is subject to a limitation that total inpatient care days for Medicare patients not exceed 20 percent of the total days for which these patients had elected hospice care.

(2) At the end of a cap period, the intermediary calculates a limitation on payment for inpatient care to ensure that Medicare payment is not made for days of inpatient care in excess of 20 percent of the total number of days of hospice care furnished to Medicare patients.

(3) If the number of days of inpatient care furnished to Medicare patients is equal to or less than 20 percent of the total days of hospice care to Medicare patients, no adjustment is necessary. Overall payments to a hospice are subject to the cap amount specified in §418.309.

(4) If the number of days of inpatient care furnished to Medicare patients exceeds 20 percent of the total days of hospice care to Medicare patients, the total payment for inpatient care is determined in accordance with the procedures specified in paragraph (f)(5) of this section. That amount is compared to actual payments for inpatient care, and any excess reimbursement must be refunded by the hospice. Overall payments to the hospice are subject to the cap amount specified in §418.309.

(5) If a hospice exceeds the number of inpatient care days described in paragraph (f)(4), the total payment for inpatient care is determined as follows:

(i) Calculate the ratio of the maximum number of allowable inpatient days to the actual number of inpatient care days furnished by the hospice to Medicare patients.

(ii) Multiply this ratio by the total reimbursement for inpatient care made by the intermediary.

(iii) Multiply the number of actual inpatient days in excess of the limitation by the routine home care rate.

(iv) Add the amounts calculated in paragraphs (f)(5)(ii) and (iii) of this section.

[48 FR 56026, Dec. 16, 1983, as amended at 56 FR 26919, June 12, 1991; 70 FR 45145, Aug. 4, 2005]

§ 418.304 Payment for physician and nurse practitioner services.

(a) The following services performed by hospice physicians and nurse practitioners are included in the rates described in § 418.302:

(1) General supervisory services of the medical director.

(2) Participation in the establishment of plans of care, supervision of care and services, periodic review and updating of plans of care, and establishment of governing policies by the physician member of the interdisciplinary group.

(b) For services not described in paragraph (a) of this section, a specified Medicare contractor pays the hospice an amount equivalent to 100 percent of the physician's reasonable charge for those physician services furnished by hospice employees or under arrangements with the hospice. Reimbursement for these physician services is included in the amount subject to the hospice payment limit described in § 418.309. Services furnished voluntarily by physicians are not reimbursable.

(c) Services of the patient's attending physician, if he or she is not an employee of the hospice or providing services under arrangements with the hospice, are not considered hospice services and are not included in the amount subject to the hospice payment limit described in § 418.309. These services are paid by the carrier under the procedures in subparts D or E, part 405 of this chapter.

(d) *Payment for hospice pre-election evaluation and counseling services.* The intermediary makes payment to the hospice for the services established in § 418.205. Payment for this service is set at an amount established under the physician fee schedule, for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity and requiring medical decision-making of low complexity other than the portion of the amount attributable to the practice expense component. Payment for this pre-election service does not count towards the hospice cap amount.

(e)(1) Effective December 8, 2003, Medicare pays for attending physician services provided by nurse practitioners to Medicare beneficiaries who have elected the hospice benefit and who have selected a nurse practitioner as their attending physician. This applies to nurse practitioners without regard to whether they are hospice employees.

(2) Nurse practitioners may bill and receive payment for services only if the—

(i) Nurse practitioner is the beneficiary's attending physician as defined in § 418.3;

(ii) Services are medically reasonable and necessary;

(iii) Services are performed by a physician in the absence of the nurse practitioner; and

(iv) Services are not related to the certification of terminal illness specified in § 418.22.

(3) Payment for nurse practitioner services are made at 85 percent of the physician fee schedule amount.

[48 FR 56026, Dec. 16, 1983, as amended at 69 FR 66426, Nov. 15, 2004; 70 FR 45145, Aug. 4, 2005]

§ 418.306 Determination of payment rates.

(a) *Applicability.* CMS establishes payment rates for each of the categories of hospice care described in § 418.302(b). The rates are established using the methodology described in section 1814(i)(1)(C) of the Act.

(b) *Payment rates.* The payment rates for routine home care and other services included in hospice care are as follows:

(1) The following rates, which are 120 percent of the rates in effect on September 30, 1989, are effective January 1, 1990 through September 30, 1990 and October 21, 1990 through December 31, 1990:

Routine home care	$75.80
Continuous home care:	
Full rate for 24 hours	442.40
Hourly rate	18.43
Inpatient respite care	78.40
General inpatient care	337.20

(2) Except for the period beginning October 21, 1990, through December 31, 1990, the payment rates for routine home care and other services included in hospice care for Federal fiscal years 1991, 1992, and 1993 and those that begin

on or after October 1, 1997, are the payment rates in effect under this paragraph during the previous fiscal year increased by the market basket percentage increase as defined in section 1886(b)(3)(B)(iii) of the Act, otherwise applicable to discharges occurring in the fiscal year. The payment rates for the period beginning October 21, 1990, through December 31, 1990, are the same as those shown in paragraph (b)(1) of this section.

(3) For Federal fiscal years 1994 through 1997, the payment rate is the payment rate in effect during the previous fiscal year increased by a factor equal to the market basket percentage increase minus—

(i) 2 percentage points in FY 1994;

(ii) 1.5 percentage points in FYs 1995 and 1996; and

(iii) 0.5 percentage points in FY 1997.

(c) *Adjustment for wage differences.* CMS will issue annually, in the FEDERAL REGISTER, a hospice wage index based on the most current available CMS hospital wage data, including any changes to the definitions of Metropolitan Statistical Areas. The payment rates established by CMS are adjusted by the intermediary to reflect local differences in wages according to the revised wage index.

(d) *Federal Register notices.* CMS publishes as a notice in the FEDERAL REGISTER any proposal to change the methodology for determining the payment rates.

[56 FR 26919, June 12, 1991, as amended at 59 FR 26960, May 25, 1994; 62 FR 42882, Aug. 8, 1997]

§ 418.307 Periodic interim payments.

Subject to the provisions of § 413.64(h) of this chapter, a hospice may elect to receive periodic interim payments (PIP) effective with claims received on or after July 1, 1987. Payment is made biweekly under the PIP method unless the hospice requests a longer fixed interval (not to exceed one month) between payments. The biweekly interim payment amount is based on the total estimated Medicare payments for the reporting period (as described in §§ 418.302–418.306). Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(5) of this chapter. Under certain circumstances that are described in § 413.64(g) of this chapter, a hospice that is not receiving PIP may request an accelerated payment.

[59 FR 36713, July 19, 1994]

§ 418.308 Limitation on the amount of hospice payments.

(a) Except as specified in paragraph (b) of this section, the total Medicare payment to a hospice for care furnished during a cap period is limited by the hospice cap amount specified in § 418.309.

(b) Until October 1, 1986, payment to a hospice that began operation before January 1, 1975 is not limited by the amount of the hospice cap specified in § 418.309.

(c) The intermediary notifies the hospice of the determination of program reimbursement at the end of the cap year in accordance with procedures similar to those described in § 405.1803 of this chapter.

(d) Payments made to a hospice during a cap period that exceed the cap amount are overpayments and must be refunded.

[48 FR 56026, Dec. 16, 1983; 48 FR 57282, Dec. 29, 1983]

§ 418.309 Hospice cap amount.

The hospice cap amount is calculated using the following procedures:

(a) The cap amount is $6,500 per year and is adjusted for inflation or deflation for cap years that end after October 1, 1984, by using the percentage change in the medical care expenditure category of the Consumer Price Index (CPI) for urban consumers that is published by the Bureau of Labor Statistics. This adjustment is made using the change in the CPI from March 1984 to the fifth month of the cap year. The cap year runs from November 1 of each year until October 31 of the following year.

(b) Each hospice's cap amount is calculated by the intermediary by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries who elected to receive hospice care from that hospice during the cap

period. For purposes of this calculation, the number of Medicare beneficiaries includes—

(1) Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care, in accordance with § 418.24, from the hospice during the period beginning on September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).

(2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total stay in all hospices that was spent in that hospice. (The hospice can obtain this information by contacting the intermediary.)

§ 418.310 Reporting and recordkeeping requirements.

Hospices must provide reports and keep records as the Secretary determines necessary to administer the program.

§ 418.311 Administrative appeals.

A hospice that believes its payments have not been properly determined in accordance with these regulations may request a review from the intermediary or the Provider Reimbursement Review Board (PRRB) if the amount in controversy is at least $1,000 or $10,000, respectively. In such a case, the procedure in 42 CFR part 405, subpart R, will be followed to the extent that it is applicable. The PRRB, subject to review by the Secretary under § 405.1874 of this chapter, shall have the authority to determine the issues raised. The methods and standards for the calculation of the payment rates by CMS are not subject to appeal.

Subpart H—Coinsurance

§ 418.400 Individual liability for coinsurance for hospice care.

An individual who has filed an election for hospice care in accordance with § 418.24 is liable for the following coinsurance payments. Hospices may charge individuals the applicable coinsurance amounts.

(a) *Drugs and biologicals.* An individual is liable for a coinsurance payment for each palliative drug and biological prescription furnished by the hospice while the individual is not an inpatient. The amount of coinsurance for each prescription approximates 5 percent of the cost of the drug or biological to the hospice determined in accordance with the drug copayment schedule established by the hospice, except that the amount of coinsurance for each prescription may not exceed $5. The cost of the drug or biological may not exceed what a prudent buyer would pay in similar circumstances. The drug copayment schedule must be reviewed for reasonableness and approved by the intermediary before it is used.

(b) *Respite care.* (1) The amount of coinsurance for each respite care day is equal to 5 percent of the payment made by CMS for a respite care day.

(2) The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began.

(3) The individual hospice coinsurance period—

(i) Begins on the first day an election filed in accordance with § 418.24 is in effect for the beneficiary; and

(ii) Ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

§ 418.402 Individual liability for services that are not considered hospice care.

Medicare payment to the hospice discharges an individual's liability for payment for all services, other than the hospice coinsurance amounts described in § 418.400, that are considered covered hospice care (as described in § 418.202). The individual is liable for the Medicare deductibles and coinsurance payments and for the difference between the reasonable and actual charge on unassigned claims on other covered services that are not considered hospice care. Examples of services

not considered hospice care include: Services furnished before or after a hospice election period; services of the individual's attending physician, if the attending physician is not an employee of or working under an arrangement with the hospice; or Medicare services received for the treatment of an illness or injury not related to the individual's terminal condition.

§418.405 Effect of coinsurance liability on Medicare payment.

The Medicare payment rates established by CMS in accordance with §418.306 are not reduced when the individual is liable for coinsurance payments. Instead, when establishing the payment rates, CMS offsets the estimated cost of services by an estimate of average coinsurance amounts hospices collect.

[56 FR 26919, June 12, 1991]

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

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AUTHORITY: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

SOURCE: 65 FR 18542, Apr. 7, 2000, unless otherwise noted.

Subpart A—General Provisions

§419.1 Basis and scope.

(a) *Basis.* This part implements section 1833(t) of the Act by establishing a prospective payment system for services furnished on or after July 1, 2000 by hospital outpatient departments to Medicare beneficiaries who are registered on hospital records as outpatients.

(b) *Scope.* This subpart describes the basis of payment for outpatient hospital services under the prospective payment system. Subpart B sets forth the categories of hospitals and services that are subject to the outpatient hospital prospective payment system and those categories of hospitals and services that are excluded from the outpatient hospital prospective payment system. Subpart C sets forth the basic

methodology by which prospective payment rates for hospital outpatient services are determined. Subpart D describes Medicare payment amounts, beneficiary copayment amounts, and methods of payment to hospitals under the hospital outpatient prospective payment system. Subpart E describes how the hospital outpatient prospective payment system may be updated. Subpart F describes limitations on administrative and judicial review. Subpart G describes the transitional payment adjustments that are made before 2004 to limit declines in payment for outpatient services.

§ 419.2 Basis of payment.

(a) *Unit of payment*. Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries. These services are identified by codes established under the Centers for Medicare & Medicaid Services Common Procedure Coding System (HCPCS). The prospective payment rate for each service or procedure for which payment is allowed under the hospital outpatient prospective payment system is determined according to the methodology described in subpart C of this part. The manner in which the Medicare payment amount and the beneficiary copayment amount for each service or procedure are determined is described in subpart D of this part.

(b) *Determination of hospital outpatient prospective payment rates: Included costs*. The prospective payment system establishes a national payment rate, standardized for geographic wage differences, that includes operating and capital-related costs that are directly related and integral to performing a procedure or furnishing a service on an outpatient basis. In general, these costs include, but are not limited to—

(1) Use of an operating suite, procedure room, or treatment room;

(2) Use of recovery room;

(3) Use of an observation bed;

(4) Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations;

(5) Supplies and equipment for administering and monitoring anesthesia or sedation;

(6) Intraocular lenses (IOLs);

(7) Incidental services such as venipuncture;

(8) Capital-related costs;

(9) Implantable items used in connection with diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;

(10) Durable medical equipment that is implantable;

(11) Implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of these devices; and

(12) Costs incurred to procure donor tissue other than corneal tissue.

(c) *Determination of hospital outpatient prospective payment rates: Excluded costs*. The following costs are excluded from the hospital outpatient prospective payment system.

(1) The costs of direct graduate medical education activities as described in §§ 413.75 through 413.83 of this chapter.

(2) The costs of nursing and allied health programs as described in § 413.85 of this chapter.

(3) The costs associated with interns and residents not in approved teaching programs as described in § 415.202 of this chapter.

(4) The costs of teaching physicians attributable to Part B services for hospitals that elect cost-based reimbursement for teaching physicians under § 415.160.

(5) The reasonable costs of anesthesia services furnished to hospital outpatients by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologists' assistants) employed by the hospital or obtained under arrangements, for hospitals that meet the requirements under § 412.113(c) of this chapter.

(6) Bad debts for uncollectible deductibles and coinsurances as described in § 413.89(b) of this chapter.

(7) Organ acquisition costs paid under Part B.

(8) Corneal tissue acquisition costs.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 70 FR 47490, Aug. 12, 2005]

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

(a) *Applicability*. The hospital outpatient prospective payment system is applicable to any hospital participating in the Medicare program, except those specified in paragraph (b) of this section, for services furnished on or after August 1, 2000.

(b) *Hospitals excluded from the outpatient prospective payment system.* (1) Those services furnished by Maryland hospitals that are paid under a cost containment waiver in accordance with section 1814(b)(3) of the Act are excluded from the hospital outpatient prospective payment system.

(2) Critical access hospitals (CAHs) are excluded from the hospital outpatient prospective payment system.

(3) A hospital located outside one of the 50 States, the District of Columbia, and Puerto Rico is excluded from the hospital outpatient prospective payment system.

(4) A hospital of the Indian Health Service.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001]

§ 419.21 Hospital outpatient services subject to the outpatient prospective payment system.

Except for services described in § 419.22, effective for services furnished on or after July 1, 2000, payment is made under the hospital outpatient prospective payment system for the following:

(a) Medicare Part B services furnished to hospital outpatients designated by the Secretary under this part.

(b) Services designated by the Secretary that are covered under Medicare Part B when furnished to hospital inpatients who are either not entitled to benefits under Part A or who have exhausted their Part A benefits but are entitled to benefits under Part B of the program.

(c) Partial hospitalization services furnished by community mental health centers (CMHCs).

(d) The following medical and other health services furnished by a comprehensive outpatient rehabilitation facility (CORF) when they are provided outside the patient's plan (of care); or by a home health agency (HHA) to patients who are not under an HHA plan or treatment; or by a hospice program furnishing services to patients outside the hospice benefit:

(1) Antigens.

(2) Splints and casts.

(3) Hepatitis B vaccine.

(e) Effective January 1, 2005, an initial preventive physical examination, as defined in § 410.16 of this chapter, if the examination is performed no later than 6 months after the individual's initial Part B coverage date that begins on or after January 1, 2005.

[65 FR 18542, Apr. 7, 2000, as amended at 67 FR 66813, Nov. 1, 2002; 69 FR 65863, Nov. 15, 2004]

§ 419.22 Hospital outpatient services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system:

(a) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(b) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(c) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(d) Certified nurse-midwife services, as defined in section 1861(gg) of the Act.

(e) Services of qualified psychologists, as defined in section 1861(ii) of the Act.

(f) Services of an anesthetist as defined in § 410.69 of this chapter.

(g) Clinical social worker services as defined in section 1861(hh)(2) of the Act.

(h) Outpatient therapy services described in section 1833(a)(8) of the Act.

(i) Ambulance services, as described in section 1861(v)(1)(U) of the Act, or, if applicable, the fee schedule established under section 1834(l).

(j) Except as provided in § 419.22(b)(11), prosthetic devices, prosthetics, prosthetic supplies, and orthotic devices.

(k) Except as provided in § 419.2(b)(10), durable medical equipment supplied by the hospital for the patient to take home.

(l) Clinical diagnostic laboratory services.

(m) Services for patients with ESRD that are paid under the ESRD composite rate and drugs and supplies furnished during dialysis but not included in the composite rate.

(n) Services and procedures that the Secretary designates as requiring inpatient care.

(o) Hospital outpatient services furnished to SNF residents (as defined in § 411.15(p) of this chapter) as part of the patient's resident assessment or comprehensive care plan (and thus included under the SNF PPS) that are furnished by the hospital ''under arrangements'' but billable only by the SNF, regardless of whether or not the patient is in a Part A SNF stay.

(p) Services that are not covered by Medicare by statute.

(q) Services that are not reasonable or necessary for the diagnosis or treatment of an illness or disease.

(r) Services defined in § 419.21(b) that are furnished to inpatients of hospitals that do not submit claims for outpatient services under Medicare Part B.

(s) Effective December 8, 2003, screening mammography services and effective January 1, 2005, diagnostic mammography services.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 69 FR 65863, Nov. 15, 2004]

Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services

§ 419.30 Base expenditure target for calendar year 1999.

(a) CMS estimates the aggregate amount that would be payable for hospital outpatient services in calendar year 1999 by summing—

(1) The total amounts that would be payable from the Trust Fund for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part; and

(2) The total amounts of coinsurance that would be payable by beneficiaries to hospitals for covered hospital outpatient services without regard to the outpatient prospective payment system described in this part.

(b) The estimated aggregate amount under paragraph (a) of this section is determined as though the deductible required under section 1833(b) of the Act did not apply.

§ 419.31 Ambulatory payment classification (APC) system and payment weights.

(a) *APC groups.* (1) CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. Except as specified in paragraph (a)(2) of this section, items and services within a group are not comparable with respect to the use of resources if the highest median cost for an item or service within the group is more than 2 times greater than the lowest median cost for an item or service within the group.

(2) CMS may make exceptions to the requirements set forth in paragraph (a)(1) in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) The payment rate determined for an APC group in accordance with § 419.32, and the copayment amount and program payment amount determined for an APC group in accordance with

subpart D of this part, apply to every HCPCS code classified within an APC group.

(b) *APC weighting factors.* (1) Using hospital outpatient claims data from calendar year 1996 and data from the most recent available hospital cost reports, CMS determines the median costs for the services and procedures within each APC group.

(2) CMS assigns to each APC group an appropriate weighting factor to reflect the relative median costs for the services within the APC group compared to the median costs for the services in all APC groups.

(c) *Standardizing amounts.* (1) CMS determines the portion of costs determined in paragraph (b)(1) of this section that is labor-related. This is known as the ''labor-related portion'' of hospital outpatient costs.

(2) CMS standardizes the median costs determined in paragraph (b)(1) of this section by adjusting for variations in hospital labor costs across geographic areas.

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

(a) *Conversion factor for 1999.* CMS calculates a conversion factor in such a manner that payment for hospital outpatient services furnished in 1999 would have equaled the base expenditure target calculated in § 419.30, taking into account APC group weights and estimated service frequencies and reduced by the amounts that would be payable in 1999 as outlier payments under § 419.43(d) and transitional pass-through payments under § 419.43(e).

(b) *Conversion factor for calendar year 2000 and subsequent years.* (1) Subject to paragraph (b)(2) of this section, the conversion factor for a calendar year is equal to the conversion factor calculated for the previous year adjusted as follows:

(i) For calendar year 2000, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point.

(ii) For calendar year 2001—

(A) For services furnished on or after January 1, 2001 and before April 1, 2001, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point; and

(B) For services furnished on or after April 1, 2001 and before January 1, 2002, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, and increased by a transitional percentage allowance equal to 0.32 percent.

(iii) For the portion of calendar year 2002 that is affected by these rules, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point, without taking into account the transitional percentage allowance referenced in § 419.32(b)(ii)(B).

(iv) For calendar year 2003 and subsequent years, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(2) Beginning in calendar year 2000, CMS may substitute for the hospital inpatient market basket percentage in paragraph (b) of this section a market basket percentage increase that is determined and applied to hospital outpatient services in the same manner that the hospital inpatient market basket percentage increase is determined and applied to inpatient hospital services.

(c) *Payment rates.* The payment rate for services and procedures for which payment is made under the hospital outpatient prospective payment system is the product of the conversion factor calculated under paragraph (a) or paragraph (b) of this section and the relative weight determined under § 419.31(b).

(d) *Budget neutrality.* (1) CMS adjusts the conversion factor as needed to ensure that updates and adjustments under § 419.50(a) are budget neutral.

(2) In determining adjustments for 2004 and 2005, CMS will not take into account any additional expenditures per section 1833(t)(14) of the Act that would not have been made but for enactment of section 621 of the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003.

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 59922, Nov. 30, 2001; 67 FR 9568, Mar. 1, 2002; 69 FR 832, Jan. 6, 2004]

EFFECTIVE DATE NOTE: At 66 FR 59922, Nov. 30, 2001, § 41932 was amended by revising paragraph (b)(1), effective Jan. 1, 2002. At 66 FR 67494, Dec. 31, 2001, paragraph (b)(1)(iii) was delayed indefinitely.

Subpart D—Payments to Hospitals

§ 419.40 Payment concepts.

(a) In addition to the payment rate described in § 419.32, for each APC group there is a predetermined beneficiary copayment amount as described in § 419.41(a). The Medicare program payment amount for each APC group is calculated by applying the program payment percentage as described in § 419.41(b).

(b) For purposes of this section—

(1) Coinsurance percentage is calculated as the difference between the program payment percentage and 100 percent. The coinsurance percentage in any year is thus defined for each APC group as the greater of the following: the ratio of the APC group unadjusted copayment amount to the annual APC group payment rate, or 20 percent.

(2) Program payment percentage is calculated as the lower of the following: the ratio of the APC group payment rate minus the APC group unadjusted copayment amount, to the APC group payment rate, or 80 percent.

(3) Unadjusted copayment amount is calculated as 20 percent of the wage-adjusted national median of charges for services within an APC group furnished during 1996, updated to 1999 using an actuarial projection of charge increases for hospital outpatient department services during the period 1996 to 1999.

(c) *Limitation of copayment amount to inpatient hospital deductible amount.* The copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

[66 FR 59922, Nov. 30, 2001]

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

(a) To calculate the unadjusted copayment amount for each APC group, CMS—

(1) Standardizes 1996 hospital charges for the services within each APC group to offset variations in hospital labor costs across geographic areas;

(2) Identifies the median of the wage-neutralized 1996 charges for each APC group; and

(3) Determines the value equal to 20 percent of the wage-neutralized 1996 median charge for each APC group and multiplies that value by an actuarial projection of increases in charges for hospital outpatient department services during the period 1996 to 1999. The result is the unadjusted beneficiary copayment amount for the APC group.

(b) CMS calculates annually the program payment percentage for every APC group on the basis of each group's unadjusted copayment amount and its payment rate after the payment rate is adjusted in accordance with § 419.32.

(c) To determine payment amounts due for a service paid under the hospital outpatient prospective payment system, CMS makes the following calculations:

(1) Makes the wage index adjustment in accordance with § 419.43.

(2) Subtracts the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the remainder by the program payment percentage for the group to determine the preliminary Medicare program payment amount.

(4) Subtracts the program payment amount from the amount determined in paragraph (c)(2) of this section to determine the copayment amount.

(i) The copayment amount for an APC cannot exceed the amount of the inpatient hospital deductible, established in accordance with § 409.82 of this chapter, for that year. For purposes of this paragraph (c)—

(A) Effective for drugs and biologicals furnished on or after January 1, 2001, the copayment amount for multiple APCs for a single drug or biological furnished on the same day will

be aggregated and treated as the copayment amount for one APC.

(B) Effective for drugs and biologicals furnished on or after July 1, 2001, the copayment amount for the APC or APCs for a drug or biological furnished on the same day will be aggregated with the copayment amount for the APC that reflects the administration of the drug or biological furnished on that day and treated as the copayment amount for one APC.

(ii) Effective for services furnished from April 1, 2001 through December 31, 2001, the national unadjusted coinsurance rate for an APC cannot exceed 57 percent of the prospective payment rate for that APC.

(iii) The national unadjusted coinsurance rate for an APC cannot exceed 55 percent in calendar years 2002 and 2003; 50 percent in calendar year 2004; 45 percent in calendar year 2005; and 40 percent in calendar year 2006 and thereafter.

(iv) The copayment amount is computed as if the adjustments under § 419.43(d) and (e) (and any adjustment made under § 419.43(f) in relation to these adjustments) had not been paid.

(5) Adds the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year to the preliminary Medicare program payment amount determined in paragraph (c)(3) of this section to determine the final Medicare program payment amount.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001]

§ 419.42 Hospital election to reduce coinsurance.

(a) A hospital may elect to reduce coinsurance for any or all APC groups on a calendar year basis. A hospital may not elect to reduce copayment amounts for some, but not all, services within the same group.

(b) A hospital must notify its fiscal intermediary of its election to reduce coinsurance no later than—

(1) June 1, 2000, for coinsurance elections for the period July 1, 2000 through December 31, 2000; or

(2) December 1 preceding the beginning of each subsequent calendar year.

(c) The hospital's election must be properly documented. It must specifically identify the APCs to which it applies and the copayment amount (within the limits identified below) that the hospital has selected for each group.

(d) The election of reduced coinsurance remains in effect unchanged during the year for which the election was made.

(e) In electing reduced coinsurance, a hospital may elect a copayment amount that is less than that year's wage-adjusted copayment amount for the group but not less than 20 percent of the APC payment rate as determined in § 419.32.

(f) The hospital may advertise and otherwise disseminate information concerning the reduced level of coinsurance that it has elected. All advertisements and information furnished to Medicare beneficiaries must specify that the coinsurance reductions advertised apply only to the specified services of that hospital and that coinsurance reductions are available only for hospitals that choose to reduce coinsurance for hospital outpatient services and are not allowed in any other ambulatory settings or physician offices.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001]

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

(a) *General rule.* CMS determines national prospective payment rates for hospital outpatient department services and determines a wage adjustment factor to adjust the portion of the APC payment and national beneficiary copayment amount attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner.

(b) *Labor-related portion of payment and copayment rates for hospital outpatient services.* CMS determines the portion of hospital outpatient costs attributable to labor and labor-related costs (known as the ''labor-related portion'' of hospital outpatient costs) in accordance with § 419.31(c)(1).

(c) *Wage index factor*. CMS uses the hospital inpatient prospective payment system wage index established in accordance with part 412 of this chapter to make the adjustment referred to in paragraph (a) of this section.

(d) *Outlier adjustment*—(1) *General rule*. Subject to paragraph (d)(4) of this section, CMS provides for an additional payment for a hospital outpatient service (or group of services) not excluded under paragraph (f) of this section for which a hospital's charges, adjusted to cost, exceed the following:

(i) A fixed multiple of the sum of—

(A) The applicable Medicare hospital outpatient payment amount determined under § 419.32(c), as adjusted under § 419.43 (other than for adjustments under this paragraph (d) or paragraph (e) of this section); and

(B) Any transitional pass-through payment under paragraph (e) of this section.

(ii) At the option of CMS, a fixed dollar amount.

(2) *Amount of adjustment*. The amount of the additional payment under paragraph (d)(1) of this section is determined by CMS and approximates the marginal cost of care beyond the applicable cutoff point under paragraph (d)(1) of this section.

(3) *Limit on aggregate outlier adjustments*—(i) *In general*. The total of the additional payments made under this paragraph (d) for covered hospital outpatient department services furnished in a year (as estimated by CMS before the beginning of the year) may not exceed the applicable percentage specified in paragraph (d)(3)(ii) of this section of the total program payments (sum of both the Medicare and beneficiary payments to the hospital) estimated to be made under this part for all hospital outpatient services furnished in that year. If this paragraph is first applied to less than a full year, the limit applies only to the portion of the year.

(ii) *Applicable percentage*. For purposes of paragraph (d)(3)(i) of this section, the term ''applicable percentage'' means a percentage specified by CMS up to (but not to exceed)—

(A) For a year (or portion of a year) before 2004, 2.5 percent; and

(B) For 2004 and thereafter, 3.0 percent.

(4) *Transitional authority*. In applying paragraph (d)(1) of this section for hospital outpatient services furnished before January 1, 2002, CMS may—

(i) Apply paragraph (d)(1) of this section to a bill for these services related to an outpatient encounter (rather than for a specific service or group of services) using hospital outpatient payment amounts and transitional pass-through payments covered under the bill; and

(ii) Use an appropriate cost-to-charge ratio for the hospital or CMHC (as determined by CMS), rather than for specific departments within the hospital.

(e) *Budget neutrality*. CMS establishes payment under paragraph (d) of this section in a budget-neutral manner excluding services and groups specified in paragraph (f) of this section.

(f) *Excluded services and groups*. Drugs and biologicals that are paid under a separate APC and devices of brachytherapy, consisting of a seed or seeds (including a radioactive source) are excluded from qualification for outlier payments.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 47677, Aug. 3, 2000; 66 FR 55856, Nov. 2, 2001; 69 FR 832, Jan. 6, 2004]

§ 419.44 Payment reductions for surgical procedures.

(a) *Multiple surgical procedures*. When more than one surgical procedure for which payment is made under the hospital outpatient prospective payment system is performed during a single surgical encounter, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts for the procedure with the highest APC payment rate; and

(2) One-half of the full program and the beneficiary payment amounts for all other covered procedures.

(b) *Terminated procedures*. When a surgical procedure is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary copayment amount are based on—

(1) The full amounts if the procedure is discontinued after the induction of anesthesia or after the procedure is started; or

(2) One-half of the full program and the beneficiary coinsurance amounts if the procedure is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before anesthesia is induced.

Subpart E—Updates

§ 419.50 Annual review.

(a) *General rule.* Not less often than annually, CMS reviews and updates groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

(b) *Consultation requirement.* CMS will consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise CMS concerning) the clinical integrity of the groups and weights. The panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting the review.

(c) *Effective dates.* CMS conducts the first annual review under paragraph (a) of this section in 2001 for payments made in 2002.

Subpart F—Limitations on Review

§ 419.60 Limitations on administrative and judicial review.

There can be no administrative or judicial review under sections 1869 and 1878 of the Act or otherwise of the following:

(a) The development of the APC system, including—

(1) Establishment of the groups and relative payment weights;

(2) Wage adjustment factors;

(3) Other adjustments; and

(4) Methods for controlling unnecessary increases in volume.

(b) The calculation of base amounts described in section 1833(t)(3) of the Act.

(c) Periodic adjustments described in section 1833(t)(9) of the Act.

(d) The establishment of a separate conversion factor for hospitals described in section 1886(d)(1)(B)(v) of the Act.

(e) The determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under § 419.43(d) or the determination of insignificance of cost, the duration of the additional payments (consistent with subpart G of this part), the determination of initial and new categories under § 419.66, the portion of the Medicare hospital outpatient fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under § 419.62(c).

[65 FR 18542, Apr. 7, 2000, as amended at 66 FR 55856, Nov. 2, 2001]

Subpart G—Transitional Pass-through Payments

SOURCE: 66 FR 55856, Nov. 2, 2001, unless otherwise noted.

§ 419.62 Transitional pass-through payments: General rules.

(a) *General.* CMS provides for additional payments under §§ 419.64 and 419.66 for certain innovative medical devices, drugs, and biologicals.

(b) *Budget neutrality.* CMS establishes the additional payments under §§ 419.64 and 419.66 in a budget neutral manner.

(c) *Uniform prospective reduction of pass-through payments.* (1) If CMS estimates before the beginning of a calendar year that the total amount of pass-through payments under §§ 419.64 and 419.66 for the year would exceed the applicable percentage (as described in paragraph (c)(2) of this section) of the total amount of Medicare payments under the outpatient prospective payment system. CMS will reduce, pro rata, the amount of each of the additional payments under §§ 419.64 and 419.66 for that year to ensure that the applicable percentage is not exceeded.

(2) The applicable percentages are as follows:

(i) For a year before CY 2004, the applicable percentage is 2.5 percent.

(ii) For 2004 and subsequent years, the applicable percentage is a percentage specified by CMS up to (but not to exceed) 2.0 percent.

(d) *CY 2002 incorporated amount.* For the portion of CY 2002 affected by these rules, CMS incorporated 75 percent of the estimated pass-through costs (before the incorporation and any pro rata reduction) for devices into the procedure APCs associated with these devices.

[66 FR 55856, 55865, Nov. 2, 2001; 67 FR 9568, Mar. 1, 2002]

EFFECTIVE DATE NOTE: At 66 FR 55865, Nov. 2, 2001, § 419.62 was amended by adding paragraph (d), effective Jan. 1, 2002. At 66 FR 67494, Dec. 31, 2001, the amendment was delayed indefinitely.

§ 419.64 Transitional pass-through payments: Drugs and biologicals.

(a) *Eligibility for pass-through payment.* CMS makes a transitional pass-through payment for the following drugs and biologicals that are furnished as part of an outpatient hospital service:

(1) *Orphan drugs.* A drug or biological that is used for a rare disease or condition and has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(2) *Cancer therapy drugs and biologicals.* A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, and a bisphosphonate if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(3) *Radiopharmaceutical drugs and biological products.* A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine services if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(4) *Other drugs and biologicals.* A drug or biological that meets the following conditions:

(i) It was first payable as an outpatient hospital service after December 31, 1996.

(ii) CMS has determined the cost of the drug or biological is not insignificant in relation to the amount payable for the applicable APC (as calculated under § 419.32(c)) as defined in paragraph (b) of this section.

(b) *Cost.* CMS determines the cost of a drug or biological to be not insignificant if it meets the following requirements:

(1) *Services furnished before January 1, 2003.* The expected reasonable cost of a drug or biological must exceed 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(2) *Services furnished after December 31, 2002.* CMS considers the average cost of a new drug or biological to be not insignificant if it meets the following conditions:

(i) The estimated average reasonable cost of the drug or biological in the category exceeds 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(ii) The estimated average reasonable cost of the drug or biological exceeds the cost of the drug or biological portion of the APC payment amount for the related service by at least 25 percent.

(iii) The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug or biological exceeds 10 percent of the APC payment amount for the related service.

(c) *Limited period of payment.* CMS limits the eligibility for a pass-through payment under this section to a period of at least 2 years, but not more than 3 years, that begins as follows:

(1) For a drug or biological described in paragraphs (a)(1) through (a)(3) of this section—August 1, 2000.

(2) For a drug or biological described in paragraph (a)(4) of this section—the date that CMS makes its first pass-through payment for the drug or biological.

(d) *Amount of pass-through payment.* Subject to any reduction determined

under § 419.62(b), the pass-through payment for a drug or biological equals the amount determined under section 1842(o) of the Social Security Act, minus the portion of the APC payment amount that CMS determines is associated with the drug or biological.

[65 FR 18542, Apr. 7, 2000, as amended at 69 FR 832, Jan. 6, 2004; 69 FR 65863, Nov. 15, 2004]

§ 419.66 Transitional pass-through payments: Medical devices.

(a) *General rule*. CMS makes a pass-through payment for a medical device that meets the requirements in paragraph (b) of this section and that is described by a category of devices established by CMS under the criteria in paragraph (c) of this section.

(b) *Eligibility*. A medical device must meet the following requirements:

(1) If required by the FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of this chapter) or another appropriate FDA exemption.

(2) The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part (as required by section 1862(a)(1)(A) of the Act).

(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.

(4) The device is not any of the following:

(i) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1).

(ii) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).

(iii) A material that may be used to replace human skin (for example, a biological or synthetic material).

(c) *Criteria for establishing device categories*. CMS uses the following criteria to establish a category of devices under this section:

(1) CMS determines that a device to be included in the category is not described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

(2) CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

(3) Except for medical devices identified in paragraph (e) of this section, CMS determines the cost of the device is not insignificant as described in paragraph (d) of this section.

(d) *Cost criteria*. CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:

(1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

(2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

(3) The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

(e) *Devices exempt from cost criteria*. The following medical devices are not subject to the cost requirements described in paragraph (d) of this section, if payment for the device was being made as an outpatient service on August 1, 2000:

(1) A device of brachytherapy.

(2) A device of temperature-monitored cryoablation.

(f) *Identifying a category for a device.* A device is described by a category, if it meets the following conditions:

(1) Matches the long descriptor of the category code established by CMS.

(2) Conforms to guidance issued by CMS relating to the definition of terms and other information in conjunction with the category descriptors and codes.

(g) *Limited period of payment for devices.* CMS limits the eligibility for a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years beginning on the date that CMS establishes a category of devices.

(h) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment amount for the device.

[66 FR 55856, Nov. 2, 2001, as amended at 67 FR 66813, Nov. 1, 2002]

Subpart H—Transitional Corridors

SOURCE: 65 FR 18542, Apr. 7, 2000, unless otherwise noted. Redesignated at 66 FR 55856, Nov. 2, 2001.

§ 419.70 Transitional adjustments to limit decline in payments.

(a) *Before 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished before January 1, 2002, for which the prospective payment system amount (as defined in paragraph (e) of this section) is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in paragraph (f) of this section), the amount of payment under this part is increased by 80 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.71 and the pre-BBA amount exceeds the product of 0.70 and the prospective payment system amount;

(3) At least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.63 and the pre-BBA amount, exceeds the product of 0.60 and the PPS amount; or

(4) Less than 70 percent of the pre-BBA amount, the amount of payment under this part shall be increased by 21 percent of the pre-BBA amount.

(b) *For 2002.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2002, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 70 percent of the amount of this difference;

(2) At least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this part is increased by the amount by which the product of 0.61 and the pre-BBA amount exceeds the product of 0.60 and the prospective payment system amount; or

(3) Less than 80 percent of the pre-BBA amount, the amount of payment under this part is increased by 13 percent of the pre-BBA amount.

(c) *For 2003.* Except as provided in paragraph (d) of this section, for covered hospital outpatient services furnished during 2003, for which the prospective payment system amount is—

(1) At least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this part is increased by 60 percent of the amount of this difference; or

(2) Less than 90 percent of the pre-BBA amount, the amount of payment under this part is increased by 6 percent of the pre-BBA amount.

(d) *Hold harmless provisions*—(1) *Temporary treatment for small rural hospitals.* For covered hospital outpatient services furnished in a calendar year before January 1, 2006 for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is located in a rural area as defined in § 412.63(b) of this chapter or is treated as being located in a rural area

under section 1886(d)(8)(E) of the Act; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

(2) *Permanent treatment for cancer hospitals and children's hospitals.* In the case of a hospital described in § 412.23(d) or § 412.23(f) of this chapter for which the prospective payment system amount is less than the pre-BBA amount for covered hospital outpatient services, the amount of payment under this part is increased by the amount of this difference.

(3) *Temporary treatment for sole community hospitals located in rural areas.* For covered hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2004, and continuing through December 31, 2005, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is a sole community hospital, under § 412.92 of this chapter; and

(ii) Is located in a rural area as defined in § 412.63(b) of this chapter or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act.

(e) *Prospective payment system amount defined.* In this paragraph, the term ''prospective payment system amount'' means, with respect to covered hospital outpatient services, the amount payable under this part for these services (determined without regard to this paragraph or any reduction in coinsurance elected under § 419.42), including amounts payable as copayment under § 419.41, coinsurance under section 1866(a)(2)(A)(ii) of the Act, and the deductible under section 1833(b) of the Act.

(f) *Pre-BBA amount defined*—(1) *General rule.* In this paragraph, the ''pre-BBA amount'' means, with respect to covered hospital outpatient services furnished by a hospital or a community mental health center (CMHC) in a year, an amount equal to the product of the reasonable cost of the provider for these services for the portions of the provider's cost reporting period (or periods) occurring in the year and the base provider outpatient payment-to-cost ratio for the provider (as defined in paragraph (f)(2) of this section).

(2) *Base payment-to-cost-ratio defined.* For purposes of this paragraph, CMS shall determine these ratios as if the amendments to sections 1833(i)(3)(B)(i)(II) and 1833(n)(1)(B)(i) of the Act made by section 4521 of the BBA, to require that the full amount beneficiaries paid as coinsurance under section 1862(a)(2)(A) of the Act are taken into account in determining Medicare Part B Trust Fund payment to the hospital, were in effect in 1996. The ''base payment-to-cost ratio'' for a hospital or CMHC means the ratio of—

(i) The provider's payment under this part for covered outpatient services furnished during one of the following periods, including any payment for these services through cost-sharing described in paragraph (e) of this section:

(A) The cost reporting period ending in 1996; or

(B) If the provider does not have a cost reporting period ending in 1996, the first cost reporting period ending on or after January 1, 1997, and before January 1, 2001; and

(ii) The reasonable costs of these services for the same cost reporting period.

(g) *Interim payments.* CMS makes payments under this paragraph to hospitals and CMHCs on an interim basis, subject to retrospective adjustments based on settled cost reports.

(h) *No effect on coinsurance.* No payment made under this section affects the unadjusted coinsurance amount or the coinsurance amount described in § 419.41.

(i) *Application without regard to budget neutrality.* The additional payments made under this paragraph—

(1) Are not considered an adjustment under § 419.43(f); and

(2) Are not implemented in a budget neutral manner.

[65 FR 18542, Apr. 7, 2000, as amended at 65 FR 67829, Nov. 13, 2000; 66 FR 59923, Nov. 30, 2001; 69 FR 832, Jan. 6, 2004; 69 FR 65863, Nov. 15, 2004]

PART 420—PROGRAM INTEGRITY: MEDICARE

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 44 FR 31142, May 30, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 420.1 Scope and purpose.

This part sets forth requirements for Medicare providers, intermediaries, and carriers to disclose ownership and control information. It also deals with access to records pertaining to certain contracts entered into by Medicare providers. These rules are aimed at protecting the integrity of the Medicare program. The statutory basis for these requirements is explained in each of the other subparts.

[51 FR 34787, Sept. 30, 1986]

§ 420.3 Other related regulations.

(a) *Appeals procedures*. Part 498 of this chapter sets forth the appeals procedures available to providers whose provider agreements CMS terminates for failure to comply with the disclosure of information requirements set forth in subpart C of this part.

(b) *Exclusion, termination, or suspension*. Part 1001 of this title sets forth the rules applicable to exclusion, termination, or suspension from the Medicare program because of fraud or abuse or conviction of program-related crimes.

[51 FR 34787, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

Subpart B [Reserved]

Subpart C—Disclosure of Ownership and Control Information

§ 420.200 Purpose.

This subpart implements sections 1124, 1124A, 1126, and 1861(v)(1)(i) of the Social Security Act. It sets forth requirements for providers, Part B suppliers, intermediaries, and carriers to disclose ownership and control information and the identities of managing employees. It also sets forth requirements for disclosure of information about a provider's or Part B supplier's owners, those with a controlling interest, or managing employees convicted of criminal offenses against Medicare, Medicaid, or the title V (Maternal and Child Health Services) and title XX (Social Services) programs.

[57 FR 27306, June 18, 1992, as amended at 60 FR 50442, Sept. 29, 1995]

§ 420.201 Definitions.

As used in this subpart unless the context indicates otherwise:

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosing entity means:

(1) A provider of services, an independent clinical laboratory, a renal disease facility, a rural health clinic, a Federally qualified health center, or a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act);

(2) A carrier or other agency or organization that is acting for one or more providers of services for purposes of part A and part B of Medicare; and

(3) A part B supplier, as defined in § 400.202 of this chapter.

Other disclosing entity means any other Medicare disclosing entity and any entity that does not participate in Medicare, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XIX, or XX of the Act. This includes:

(1) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, items or services for which payment may be claimed by the entity under any plan or program established under title V of the Social Security Act or under an approved State Medicaid plan;

(2) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which payment may be claimed by the entity under an approved State plan and services program under title XX of the Act; or

(3) A Medicaid fiscal agent.

Group of practitioners means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

Indirect ownership interest means any ownership interest in an entity that has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

Managing employee means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the institution, organization, or agency.

Ownership interest means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

Person with an ownership or control interest means a person or corporation that—

(1) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(2) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(3) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(4) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(5) Is an officer or director of a disclosing entity that is organized as a corporation; or

(6) Is a partner in a disclosing entity that is organized as a partnership.

Significant business transaction means any business transaction or series of transactions during any one fiscal year, the total of which exceeds the lesser of $25,000 and 5 percent of the total operating expenses of the provider.

Subcontractor means—

(1) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(2) An individual, agency, or organization with which an intermediary or carrier has entered into a contract, agreement, purchase order or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicare agreement.

Wholly owned supplier means a supplier whose total ownership interest is

held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41642, July 17, 1979, as amended at 57 FR 24982, June 12, 1992; 57 FR 27306, June 18, 1992; 57 FR 35760, Aug. 11, 1992]

§ 420.202 Determination of ownership or control percentages.

(a) *Indirect ownership interest.* The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the disclosing entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

(b) *Person with an ownership or control interest.* In order to determine the percentage of ownership interest in any mortgage, deed of trust, note, or other obligation, the percentage of interest owned in obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. Conversely, if B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported.

§ 420.203 Disclosure of hiring of intermediary's former employees.

A provider must notify the Secretary promptly if it, or its home office (in the case of a chain organization), employs or obtains the services of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity by an agency or organization which currently serves, or at any time during the preceding year, served as a Medicare fiscal intermediary or carrier for the provider. *Similar capacity* means the performance of essentially the same work functions as those of a manager, accountant, or auditor even though the individual is not so designated by title.

§ 420.204 Principals convicted of a program-related crime.

(a) *Information required.* Prior to CMS's acceptance of a provider agreement or issuance or reissuance of a supplier billing number, or at any time upon written request by CMS, the provider or part B supplier must furnish CMS with the identity of any person who:

(1) Has an ownership or control interest in the provider or part B supplier;

(2) Is an agent or managing employee of the provider or part B supplier; or

(3) Is a person identified in paragraph (a)(1) or (a)(2) of this section and has been convicted of, or was an owner of, had a controlling interest in, or was a managing employee of a corporation that has been convicted of a criminal offense, subjected to any civil monetary penalty, or excluded from the programs for any activities related to involvement in the Medicare, Medicaid, title V or title XX social services program, since the inception of those programs.

(b) *Refusal to enter into or renew agreement or to issue or reissue billing numbers.* CMS may refuse to enter into or renew an agreement with a provider of services, or to issue or reissue a billing number to a part B supplier, if any person who has an ownership or control interest in the provider or supplier, or who is an agent or managing employee, has been convicted of a criminal offense or subjected to any civil penalty or sanction related to the involvement of that person in Medicare, Medicaid, title V or title XX social services programs. In making this decision, CMS considers the facts and circumstances of the specific case, including the nature and severity of the crime, penalty or sanction and the extent to which it adversely affected beneficiaries and the programs involved. CMS also considers whether it has been given reasonable assurance that the person will not commit any further criminal or civil offense against the programs.

(c) *Notification of Inspector General.* CMS promptly notifies the Inspector

General of the Department of the receipt of any application or request for participation, certification, re-certification, or for a billing number that identifies any person described in paragraph (a)(3) of this section and the action taken on that application or request.

[57 FR 27306, June 18, 1992]

§ 420.205 Disclosure by providers and part B suppliers of business transaction information.

A provider or part B supplier must submit to CMS, within 35 days after the date of a written request, full and complete information on—

(a) The ownership of a subcontractor with which the provider or part B supplier has had, during the previous 12 months, business transactions in an aggregate amount in excess of $25,000;

(b) Any significant business transactions between the provider or part B supplier and any wholly owned supplier or between the provider or part B supplier and any subcontractor, during the 5 year period ending on the date of the request;

(c) The names of managing employees of the subcontractors;

(d) The identity of any other entities to which payment may be made by Medicare, which a person with an ownership or control interest or a managing employee in the subcontractor has or has had an ownership or control interest in the 3-year period preceding disclosure; and

(e) Any penalties, assessments, or exclusions under sections 1128, 1128A and 1128B of the Act incurred by the subcontractor, its owners, managing employees or those with a controlling interest in the subcontract.

[57 FR 27306, June 18, 1992]

§ 420.206 Disclosure of persons having ownership, financial, or control interest.

(a) *Information that must be disclosed.* A disclosing entity must submit the following information in the manner specified in paragraph (b) of this section:

(1) The name and address of each person with an ownership or control interest in the entity or in any subcontractor in which the entity has direct or indirect ownership interest totaling 5 percent or more. In the case of a part B supplier that is a joint venture, ownership of 5 percent or more of any company participating in the joint venture should be reported. Any physician who has been issued a Unique Physician Identification Number by the Medicare program must provide this number.

(2) Whether any of the persons named, in compliance with paragraph (a)(1) of this section, is related to another as spouse, parent, child, or sibling.

(3) The name of any other disclosing entity in which any person with an ownership or control interest, or who is a managing employee in the reporting disclosing entity, has, or has had in the previous three-year period, an ownership or control interest or position as managing employee, and the nature of the relationship with the other disclosing entity. If any of these other disclosing entities has been convicted of a criminal offense or received a civil monetary or other administrative sanction related to participation in Medicare, Medicaid, title V (Maternal and Child Health) or title XX (Social Services) programs, such as penalties assessments and exclusions under sections 1128, 1128A or 1128B of the Act, the disclosing entity must also provide that information.

(b) *Time and manner of disclosure.* (1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicare standards must supply the information specified in paragraph (a) of this section to the State survey agency at the time it is surveyed. The survey agency will promptly furnish the information to the Secretary.

(2) Any disclosing entity that is not subject to periodic survey and certification must supply the information specified in paragraph (a) of this section to CMS before entering into a contract or agreement with Medicare or before being issued or reissued a billing number as a part B supplier.

(3) A disclosing entity must furnish updated information to CMS at intervals between recertification, or re-enrollment, or contract renewals, within 35 days of a written request. In the case of a part B supplier, the supplier must

report also within 35 days, on its own initiative, any changes in the information it previously supplied.

(c) *Consequences of failure to disclose.* (1) CMS does not approve an agreement or contract with, or make a determination of eligibility for, or (in the case of a part B supplier) issue or reissue a billing number to, any disclosing entity that fails to comply with paragraph (b) of this section.

(2) CMS terminates any existing agreement or contract with, or withdraws a determination of eligibility for or (in the case of a part B supplier) revokes the billing number of, any disclosing entity that fails to comply with paragraph (b) of this section.

(d) *Public disclosure.* Information furnished to the Secretary under the provisions of this section shall be subject to public disclosure as specified in 20 CFR part 422.

[44 FR 41642, July 17, 1979, as amended at 57 FR 27306, June 18, 1992]

Subpart D—Access to Books, Documents, and Records of Subcontractors

SOURCE: 47 FR 58267, Dec. 30, 1982, unless otherwise noted.

§ 420.300 Basis, purpose, and scope.

This subpart implements section 1861(v)(1)(I) of the Act, which requires, for Medicare payment under certain provider contracts, access by the Secretary, upon written request, and the Comptroller General, and their duly authorized representatives, to certain contracts for services and to books, documents, and records necessary to verify the costs of the services. The contracts affected are those between providers and their subcontractors, and between the subcontractors and organizations related to the subcontractor by control or common ownership. It also specifies the criteria by which HHS will determine whether to request access to books, documents, and records.

§ 420.301 Definitions.

For purposes of this subpart—

Books, documents, and records means all writings, recordings, transcriptions and tapes of any description necessary to verify the nature and extent of the costs of the services provided by the subcontractor.

Common ownership means that an individual or individuals possess significant ownership or equity in the subcontractor and the entity providing the services under the contract.

Contract for services means a contract through which a provider obtains the performance of an act or acts, as distinguished from supplies or equipment. It includes any contract for both goods and services to the extent the value or cost of the service component is $10,000 or more within a 12-month period.

Control means that an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions of policies of an organization.

Provider means a hospital, skilled nursing facility, home health agency, hospice or comprehensive outpatient rehabilitation facility, or a related organization (as defined in § 413.17 of this chapter) of any of these providers.

Related to the subcontractor means that the subcontractor is, to a significant extent, associated or affiliated with, owns, or is owned by, or has control of or is controlled by, the organization furnishing the services, facilities, or supplies.

Subcontractor means any entity, including an individual or individuals, that contracts with a provider to supply a service, either to the provider or directly to a beneficiary, for which Medicare reimburses the provider the cost of the service. This includes organizations related to the subcontractor that have a contract with the subcontractor for which the cost or value is $10,000 or more in a 12-month period.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984; 51 FR 34833, Sept. 30, 1986]

§ 420.302 Requirement for access clause in contracts.

(a) *Applicability.* This subpart applies to contracts—

(1) Between a provider and a subcontractor and, where subject to section 1861(v)(l)(I)(ii) of the Act, between a subcontractor and an organization related to the subcontractor;

(2) Entered into or renewed after December 5, 1980; and

(3) For services the cost or value of which is $10,000 or more over a 12-month period, including contracts for both goods and services in which the service component is worth $10,000 or more over a 12-month period.

(b) *Requirement.* Any contract meeting the conditions of paragraph (a) of this section must include a clause that allows the Comptroller General of the United States, HHS, and their duly authorized representatives access to the subcontractor's contract, books, documents, and records until the expiration of four years after the services are furnished under the contract or subcontract. The access must be provided for in accordance with the provisions of this subpart. The clause must also allow similar access by HHS, the Comptroller General, and their duly authorized representatives to contracts subject to section 1861(v)(l)(I)(ii) of the Act between a subcontractor and organizations related to the subcontractor and to books, documents, and records.

(c) *Prohibition against Medicare reimbursement.* If a contract subject to the requirements of this subpart does not contain the clause required by paragraph (b) of this section, CMS will not reimburse the provider for the cost of the services furnished under the contract and will recoup any payments previously made for services under the contract. However, in order to avoid nonreimbursement or recoupment, providers will have until July 30, 1983, to amend those contracts entered into or renewed after December 5, 1980, and before January 31, 1983, that do not conform to the requirements of paragraph (b) of this section.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984]

§ 420.303 HHS criteria for requesting books, documents, and records.

HHS will generally request books, documents, and records from a subcontractor only if one of the following situations exists and the question cannot satisfactorily and efficiently be resolved without access to the books, documents, and records:

(a) HHS has reason to believe that the costs claimed for services of the subcontractor are excessive or inappropriate.

(b) There is insufficient information to judge the appropriateness of the costs.

(c) There is a written accusation with suitable evidence against the provider or subcontractor of kickbacks, bribes, rebates, or other illegal activities.

(d) There is evidence of a possible nondisclosure of the existence of a related organization.

§ 420.304 Procedures for obtaining access to books, documents, and records.

(a) *Contents of the request.* Requests for access will be in writing and contain the following elements:

(1) Reasonable identification of the books, documents, and records to which access is being requested.

(2) Identification of the contract or subcontract in which costs are being questioned as excessive or inappropriate.

(3) The reason that the appropriateness of the costs or value of the services of the subcontractor in question cannot be adequately or efficiently determined without access to the subcontractor's books and records.

(4) The authority in the statute and regulations for the access requested.

(5) To the extent possible, the identification of those individuals who will be visiting the subcontractor to obtain access to the books, documents, and records.

(6) The time and date of the scheduled visit.

(7) The name of the duly authorized representative of HHS to contact if there are any questions.

(b) *Subcontractor response to a request for access to books, documents, and records.* (1) The subcontractor will have 30 days from the date of a written request for access to books, documents, and records to make them available in accordance with the request.

(2) If the subcontractor believes the request is inadequate because it does not fully meet one or more of the required elements in paragraph (a) of this section, the subcontractor must advise the requesting organization of the additional information needed.

(i) The subcontractor must notify the requesting organization within 20 days of the date of the request that it was improperly completed.

(ii) The subcontractor must make the books, documents, and records available within 20 days after the date of the requesting organization's response.

(3) If the subcontractor believes, for good cause, that the requested books, documents, and records cannot be made available as requested with the 30-day period under paragraph (b)(1) of this section, the subcontractor may request an extension of time within which to comply with the request from the requesting organization. The requesting organization may, at its discretion, grant the request for an extension, in whole or in part, for good cause shown.

(4) The subcontractor must make the books, documents, and records available during its regular business hours for inspection, audit, and reproduction.

(5) If HHS asks the subcontractor to reproduce books, documents, and records, HHS will pay the reasonable cost of reproduction. However, if the subcontractor reproduces books, documents, and records as a means of making them available, the subcontractor must bear the cost of the reproduction and no Medicare reimbursement will be made for that purpose.

(6) HHS reserves the right to examine the originals of any requested contracts, books, documents, and records, if they exist.

(c) *Refusal by subcontractor to furnish access to records.* If CMS determines that the books, documents, and records are necessary for the reimbursement determination and the subcontractor refuses to make them available, HHS may initiate legal action against the subcontractor.

Subpart E—Rewards for Information Relating to Medicare Fraud and Abuse, and Establishment of a Program to Collect Suggestions for Improving Medicare Program Efficiency and to Reward Suggesters for Monetary Savings

SOURCE: 63 FR 31128, June 8, 1998, unless otherwise noted.

§ 420.400 Basis and scope.

This subpart implements sections 203(b) and (c) of Public Law 104–191, which require the establishment of programs to encourage individuals to report suspected cases of fraud and abuse and submit suggestions on methods to improve the efficiency of the Medicare program. Sections 203(b) and (c) of Public Law 104–191 also provide the authority for CMS to reward individuals for reporting fraud and abuse and for submitting suggestions that could improve the efficiency of the Medicare program. This subpart sets forth procedures for rewarding individuals.

[64 FR 66401, Nov. 26, 1999]

§ 420.405 Rewards for information relating to Medicare fraud and abuse.

(a) *General rule.* CMS pays a monetary reward for information that leads to the recovery of at least $100 of Medicare funds from individuals and entities that are engaging in, or have engaged in, acts or omissions that constitute grounds for the imposition of a sanction under section 1128, section 1128A, or section 1128B of the Act or that have otherwise engaged in sanctionable fraud and abuse against the Medicare program. The determination of whether an individual meets the criteria for an award, and the amount of the award, is at the discretion of CMS. CMS pays rewards only if a reward is not otherwise provided for by law. When CMS applies the criteria specified in paragraphs (b), (c), and (e) of this section to determine the eligibility and the amount of the reward, it notifies the recipient as specified in paragraph (d) of this section.

(b) *Information eligible for reward.* (1) In order for an individual to be eligible to receive a reward, the information he

or she supplied must relate to the activities of a specific individual or entity and must specify the time period of the alleged activities.

(2) CMS does not give a reward for information relating to an individual or entity that, at the time the information is provided, is already the subject of a review or investigation by CMS or its contractors, or the OIG, the Department of Justice, the Federal Bureau of Investigation, or any other Federal, State, or local law enforcement agency.

(c) *Persons eligible to receive a reward*—(1) *General rule.* Any person (other than one excluded under paragraph (c)(2) of this section) is eligible to receive a reward under this section if the person submits the information in the manner set forth in paragraph (f) of this section.

(2) *Excluded individuals.* (i) An individual who was, or is an immediate family member of, an officer or employee of HHS or its contractors, the SSA, the OIG, a State Medicaid Agency, or the Department of Justice, the Federal Bureau of Investigation, or any other Federal, State, or local law enforcement agency at the time he or she came into possession of, or divulged, information leading to a recovery of Medicare funds is not eligible to receive a reward under this section.

(ii) Any other Federal or State employee or contractor or an HHS grantee is not eligible for a reward under this section if the information submitted came to his or her knowledge in the course of his or her official duties.

(iii) An individual who illegally obtained the information he or she submitted is excluded from receiving a reward under this section.

(iv) An individual who participated in the sanctionable offense with respect to which payment would be made is excluded from receiving a reward under this section.

(d) *Notification of eligibility*—(1) *General rule.* After all Medicare funds have been recovered and CMS has determined a participant eligible to receive a reward under the provisions of this section, it notifies the informant of his or her eligibility, by mail, at the most recent address supplied by the individual. It is the individual's responsibility to ensure that the reward program has been notified of any change in his or her address or other relevant personal information (for example, change of name, phone number).

(2) *Special circumstances.* (i) If the individual has relocated to an unknown address, the individual or his or her legal representative may claim the reward by contacting CMS within 1 year from the date on which CMS first attempted to notify the individual about a reward. CMS does not consider the individual or his or her legal representative eligible for a reward more than 1 year after the date on which it first attempted to give notice. CMS does not pay interest on rewards that are not immediately claimed.

(ii) If the individual has become incapacitated or has died, an executor, administrator, or other legal representative may claim the reward on behalf of the individual or the individual's estate. The claimant must submit certified copies of the letters testamentary, letters of administration, or other similar evidence to show his or her authority to claim the reward. The claim must be filed within 1 year from the date on which CMS first gave or attempted to give notice of the reward.

(e) *Amount and payment of reward.* (1) In determining whether it will pay a reward and, if so, the amount of the reward, CMS takes into account all relevant factors, including the significance of the information furnished in relation to the ultimate resolution of the case and the recovery of Medicare funds.

(2) The amount of a reward represents what CMS considers to be adequate compensation in the particular case, not to exceed 10 percent of the overpayments recovered in the case or $1,000, whichever is less.

(3) If more than one person is eligible to receive a reward in a particular case, CMS allocates the total reward amount (not to exceed 10 percent of the overpayments recovered in that case or $1,000, whichever is less) among the participants.

(4) CMS bases rewards only on recovered Medicare payments and not on amounts collected as penalties or fines.

(5) CMS makes payments as promptly as the circumstances of the case permit, but not until it has collected all Medicare overpayments, fines, and penalties.

(6) No person may make any offer or promise or otherwise bind CMS or HHS with respect to the payment of any reward under this section or the amount of the reward.

(f) *Submission of information.* (1) An individual may submit information on persons or entities engaging in, or that have engaged in, fraud and abuse against the Medicare program to the Office of the Inspector General, or to the Medicare intermediary or carrier that has jurisdiction over the suspected fraudulent provider or supplier.

(2) A participant interested in receiving a reward must provide his or her name, address, telephone number, and any other requested identifying information so that he or she may be contacted, if necessary, for additional information and, when applicable, for the payment of a reward upon resolution of the case.

(g) *Confidentiality.* CMS does not reveal a participant's identity to any person, except as required by law.

(h) *Finding of ineligibility after reward is accepted.* If, after a reward is accepted, CMS finds that the awardee was ineligible to receive the reward, the Government is not liable for the reward and the awardee must refund all monies received.

§ 420.410 Establishment of a program to collect suggestions for improving Medicare program efficiency and to reward suggesters for monetary savings.

(a) *Definitions.* As used in this section, the following definitions apply:

Payment means a monetary award given to a suggester in recognition of, and as a reward for, a suggestion adopted by CMS that improves the efficiency of, and results in monetary savings to, the Medicare program.

Savings means the monetary value of the net benefits the Medicare program derives from implementing the suggestion.

Suggester means an individual, a group of individuals, or a legal entity such as a corporation, partnership, or professional association, not otherwise excluded under § 420.410(d), who submits a suggestion under this section.

Suggestion means an original idea submitted in writing.

Suggestion program means the specific procedures and requirements established by CMS for receiving suggestions from the suggester on methods to improve the efficiency of the Medicare program, evaluating the suggestions and, if appropriate, paying a reward to the suggester for adopted suggestions that result in improved efficiency and produce monetary savings to the Medicare program.

(b) *General rule.* CMS may make payment for adopted suggestions that increase the efficiency of the Medicare program and result in monetary savings. CMS only makes payment for suggestions in instances in which a reward is not otherwise provided by law. The determination to adopt a suggestion, to reward the suggester, and the method of calculating a reward are at the sole discretion of CMS.

(c) *Eligibility.* Except as specified in paragraph (d) of this section, any individual, group of individuals or legal entity, such as a corporation, partnership or professional association, is eligible to submit a suggestion and be considered for a reward under this suggestion program if the suggestion is submitted to CMS in the manner set forth in paragraph (e) of this section.

(d) *Exclusions.* Medicare contractors, their officers and employees, individuals who work for Federal agencies under a contract, employees of Federally-sponsored research and demonstration projects, Federal officers and employees, and immediate family members of these individuals, are excluded from receiving payment under the suggestion program. If, after the suggester receives a reward payment, CMS determines that the suggester was ineligible to receive the reward, CMS is not liable for the reward payment and the suggester must refund all monies received.

(e) *Requirements for submitting suggestions*—(1) To be considered, the suggestion must be in writing, mailed to CMS, and must include the following information:

(i) A description of an existing problem or need;

(ii) A suggested method for solving the problem or filling the need; and

(iii) If known, an estimate of the savings potential that could result from implementing the suggestion.

(2) Suggestions must be mailed to: Centers for Medicare & Medicaid Services Suggestion Program, 7500 Security Blvd., Baltimore, Maryland 21244–1850.

(3) Any suggesters interested in receiving a reward must provide CMS with the following information: An individual suggester must provide his or her name, a group of suggesters must provide the names of all the group members, and a legal entity must provide its name and the name of its representative. All suggesters must provide an address, telephone number, and any other identifying information that CMS needs to contact the suggester for additional information and, where applicable, to mail the reward.

(f) *Evaluation process*—(1) *Relevant factors*. CMS evaluates all suggestions on the basis of the following factors:

(i) Originality of suggestion.

(ii) An estimate of potential monetary savings to the Medicare program.

(iii) The extent to which Medicare program efficiency would be improved if CMS adopts the suggestion.

(iv) Accuracy of the information reflected in the suggestion.

(v) Feasibility of implementation.

(vi) Nature and complexity of the suggestion.

(vii) Any other factors that appear to be relevant.

(2) *Evaluation time limit*. CMS concludes the evaluation process in a reasonable amount of time, not to exceed 2 years from the receipt date, taking into consideration the complexity of the suggestion, the number of possible implementation strategies, and CMS's current workload.

(g) *Basis for reward payment*—(1) *General rule*. If CMS determines that it is appropriate to make a reward payment for a suggestion adopted in whole or in part, that results in improved efficiency and monetary savings to the Medicare program, the payment is based on—

(i) The actual first-year net savings to the Medicare program, or

(ii) The average annual net savings to the Medicare program expected to be realized over a period of not more than 3 years if—

(A) An improvement is expected to yield monetary savings for more than 1 year and implementation involves substantial costs; or

(B) Monetary savings are negligible in the first year but are expected to substantially increase in subsequent years.

(2) *Reward payment amount*. CMS determines the amount of a reward payment using the following formula:

(i) Net savings from $1,000 to $10,000—10 percent of the savings, with a minimum award amount of $100;

(ii) Net savings of $10,001 to $100,000—$1,000 for the first $10,000 of savings, plus 3 percent of the net savings over $10,000;

(iii) Net savings of more than $100,000—$3,700 for the first $100,000 of savings, plus 0.5 percent of savings over $100,000, with a maximum award amount of $25,000.

(h) *Adoption of suggestion and issuance of reward payment*—(1) *Adoption*. Upon completing its evaluation, CMS decides whether to adopt a suggestion. If CMS receives the same or an overlapping suggestion from two or more unrelated parties, CMS will consider a reward only for the suggestion CMS received first, if the suggestion or overlapping part of the suggestion are identical, and CMS has adopted that part. If the suggestions are not identical, CMS will consider rewarding the suggestion received first, if it is feasible and CMS is able to adopt and implement the suggestion. If the first suggestion cannot be implemented, CMS may consider rewarding the suggestion received next, even if it is similar, provided CMS can adopt and implement the suggestion.

(2) *Issuance of reward payment*. After the reward payment amount is determined, as described in paragraph (g) of this section, CMS mails payment to the suggester (or to the legal representatives referenced in paragraph (k) of this section) only after the suggestion has been in operation for 1 year.

(i) *Group suggestions*. When CMS deems that a reward payment is appropriate for a suggestion submitted by a group of individuals, CMS pays an equal share of the reward to each of the

individuals identified in the group. If an organization such as a corporation, partnership, or professional association submits a suggestion, CMS makes a single reward payment to that organization.

(j) *Change in name or address.* It is the suggester's responsibility to notify CMS of any change of address or other relevant information. If the suggester fails to update CMS on any change in this information, and the reward payment mailed to the suggester is returned to CMS, the suggester must claim the reward payment by contacting CMS within 1 year from the date CMS first mailed the reward payment to the suggester. CMS does not pay interest on rewards that, for any reason, are delayed or are not immediately claimed.

(k) *Incapacitated or deceased suggester.* If the suggester is incapacitated or has died, an executor, administrator, or other legal representative may claim the reward on behalf of the suggester or the suggester's estate. The claimant must submit certified copies of the letters testamentary, letters of administration, or other similar evidence to CMS showing his or her authority to claim the reward. The claim must be filed within 1 year from the date on which CMS first attempted to pay the reward to the individual who submitted the suggestion.

(l) *Maintenance of records*—(1) CMS retains records related to the administration of the suggestion program in accordance with 36 CFR part 1228 (the regulations for the National Archives and Records Administration).

(2) CMS does not disclose information submitted under the suggestion program, except as required by law.

[64 FR 66401, Nov. 26, 1999]

PART 421—INTERMEDIARIES AND CARRIERS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 45 FR 42179, June 23, 1980, unless otherwise noted.

Subpart A—Scope, Definitions, and General Provisions

§ 421.1 Basis and scope.

(a) This part is based on the indicated provisions of the following sections of the Act:

1124—Requirements for disclosure of certain information.

1816 and 1842—Use of organizations and agencies in making Medicare payments to providers and suppliers of services.

(b) Section 421.118 is also based on 42 U.S.C.1395b–1(a)(1)(F), which authorizes demonstration projects involving intermediary agreements and carrier contracts.

(c) The provisions of this part apply to agreements with Part A (Hospital Insurance) intermediaries and contracts with Part B (Supplementary Medical Insurance) carriers. They also state that CMS may perform certain functions directly or by contract. They specify criteria and standards to be used in selecting intermediaries and evaluating their performance, in assigning or reassigning a provider or providers to particular intermediaries, and in designating regional or national intermediaries for certain classes of providers. The provisions set forth the instances where there is the opportunity for a hearing for intermediaries and carriers affected by certain adverse actions. In some circumstances, the adversely affected intermediaries may request a judicial review of hearings decisions on—

(1) Assignment or reassignment of a provider or providers; or

(2) Designation of an intermediary or intermediaries to serve a class of providers.

[49 FR 3659, Jan. 30, 1984, as amended at 60 FR 50442, Sept. 29, 1995]

§421.3 Definitions.

Intermediary means an entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis (or under the Prospective Payment System for hospitals) and to perform other related functions. For purposes of designating regional or alternative regional intermediaries for home health agencies and of designating intermediaries for hospices under §421.117 as well as for applying the performance criteria in §421.120 and the performance standards in §421.122 and any adverse action resulting from such application, the term intermediary also means a Blue Cross Plan which has entered into a subcontract approved by CMS with the Blue Cross and Blue Shield Association to perform intermediary functions.

[59 FR 681, Jan. 6, 1994]

§421.5 General provisions.

(a) *Competitive bidding not required for carriers.* CMS may enter into contracts with carriers, or with intermediaries to act as carriers in certain circumstances, without regard to section 3709 of the U.S. Revised Statutes or any other provision of law that requires competitive bidding.

(b) *Indemnification of intermediaries and carriers.* Intermediaries and carriers act on behalf of CMS in carrying out certain administrative responsibilities that the law imposes. Accordingly, their agreements and contracts contain clauses providing for indemnification with respect to actions taken on behalf of CMS and CMS is the real party of interest in any litigation involving the administration of the program.

(c) *Use of intermediaries to perform carrier functions.* CMS may contract with an intermediary to perform carrier functions with respect to services for which Part B payment is made to a provider.

(d) *Nonrenewal of agreement or contract.* Notwithstanding any of the provisions of this part, CMS has the authority not to renew an agreement or contract when its term expires.

(e) *Intermediary availability in an area.* For more effective and efficient administration of the program, CMS retains the right to expand or diminish the geographical area in which an intermediary is available to serve providers.

(f) *Provision for automatic renewal.* Agreements and contracts under this part may contain automatic renewal clauses for continuation from term to term unless either party gives notice, within timeframes specified in the agreement or contract, of its intention not to renew.

[45 FR 42179, June 23, 1980, as amended at 54 FR 4026, Jan. 27, 1989]

Subpart B—Intermediaries

§421.100 Intermediary functions.

An agreement between CMS and an intermediary specifies the functions to be performed by the intermediary, which must include, but are not necessarily limited to, the following:

(a) *Coverage.* (1) The intermediary ensures that it makes payments only for services that are:

(i) Furnished to Medicare beneficiaries;

(ii) Covered under Medicare; and

(iii) In accordance with QIO determinations when they are services for which the QIO has assumed review responsibility under its contract with CMS.

(2) The intermediary takes appropriate action to reject or adjust the claim if—

(i) The intermediary or the QIO determines that the services furnished or proposed to be furnished were not reasonable, not medically necessary, or not furnished in the most appropriate setting; or

(ii) The intermediary determines that the claim does not properly reflect the kind and amount of services furnished.

(b) *Fiscal management.* The intermediary must receive, disburse, and account for funds in making Medicare payments.

(c) *Provider audits.* The intermediary must audit the records of providers of services as necessary to assure proper payments.

(d) *Utilization patterns.* The intermediary must assist providers to—

(1) Develop procedures relating to utilization practices;

(2) Make studies of the effectiveness of those procedures and recommend methods to improve them;

(3) Evaluate the results of utilization review activity; and

(4) Assist in the application of safeguards against unnecessary utilization of services.

(e) *Resolution of cost report disputes.* The intermediary must establish and maintain procedures approved by CMS to consider and resolve any disputes that may result from provider dissatisfaction with an intermediary's determinations concerning provider cost reports.

(f) *Reconsideration of determinations.* The intermediary must establish and maintain procedures approved by CMS for the reconsideration of its determinations to deny payments to an individual or to the provider that furnished services to the individual. The QIO performs reconsideration of cases in which it made a determination subject to reconsideration.

(g) *Information and reports.* The intermediary must furnish to CMS any information and reports that CMS requests in order to carry out its responsibilities in the administration of the Medicare program.

(h) *Other terms and conditions.* The intermediary must comply with all applicable laws and regulations and with any other terms and conditions included in its agreement.

(i) *Dual intermediary responsibilities.* With respect to the responsibility for service to provider-based HHAs and provider-based hospices, where the HHA or hospice and its parent provider will be served by different intermediaries under § 421.117 of this part, the designated regional intermediary will process bills, make coverage determinations and make payments to the HHAs and hospices. The intermediary serving the parent provider will perform all fiscal functions, including audits and settlement of the Medicare cost reports and the HHA and hospice supplement worksheets.

[45 FR 42179, June 23, 1980, as amended at 48 FR 7178, Feb. 18, 1983; 49 FR 3659, Jan. 30, 1984; 51 FR 43198, Dec. 1, 1986; 53 FR 17944, May 19, 1988; 54 FR 4026, Jan. 27, 1989]

§ 421.103 Options available to providers and CMS.

(a) Except for hospices (which are covered under § 421.117), a provider may elect to receive payment for covered services furnished to Medicare beneficiaries—

(1) Directly from CMS (subject to the provisions of paragraph (b) of this section); or

(2) Through an intermediary, when both CMS and the intermediary consent.

(b) Whenever CMS determines it appropriate, it may contract with any organization (including an intermediary with which CMS has previously entered into an agreement under § 421.105 and § 421.110 or designated as a regional or alternative regional intermediary under § 421.117) for the purposes of making payments to any provider that does

not elect to receive payment from an intermediary.

[49 FR 3659, Jan. 30, 1984; 49 FR 9174, Mar. 12, 1984]

§421.104 Nominations for intermediary.

(a) *Nomination by groups or associations of providers.* (1) An association of providers, except for hospices, may nominate an organization or agency to serve as intermediary for its members.

(2) The nomination is not binding on any member of the association if it notifies CMS of its nonconcurrence with the nomination.

(3) The nomination must be made in writing, to CMS, and must—

(i) Identify the proposed intermediary by giving the complete name and address;

(ii) Include, or furnish as an attachment, the name, address, and bed capacity (or patient care capacity in the case of home health agencies) of each member of the association;

(iii) List the members that have concurred in the nomination of the proposed intermediary; and

(iv) Be signed by an authorized representative of the association.

(b) *Action by nonmembers or nonconcurring members.* Providers that nonconcur in their association's nomination, or are not members of an association, may—

(1) Form a group of 2 or more providers for the specific purpose of nominating an intermediary, in accordance with provisions of paragraph (a) of this section;

(2) Elect to receive payments from a fiscal intermediary with which CMS already has an agreement, if CMS and the intermediary agree to it (see §421.106); or

(3) Elect to receive payment from CMS as provided in §421.103.

(c) CMS is not required to enter into an agreement with a proposed intermediary solely because it has been nominated.

[45 FR 42179, June 23, 1980, as amended at 48 FR 56035, Dec. 16, 1983; 49 FR 3659, Jan. 30, 1984]

§421.105 Notification of action on nomination.

(a) CMS will send, to each member of a nominating association or group, written notice of a decision to enter into or not enter into an agreement with the nominated organization or agency.

(b) Any member of a group or association having more than one nominated intermediary approved by CMS to act on its behalf must withdraw its nomination from all but one or exercise the option provided in §421.103(a), subject to §421.103(b), to receive payment directly from CMS.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

§421.106 Change to another intermediary or to direct payment.

(a) Any provider may request a change of intermediary, or except for a hospice, that it be paid directly by CMS, by—

(1) Giving CMS written notice of its desire at least 120 days before the end of its current fiscal year; and

(2) Concurrently giving written notice to its intermediary.

(b) If CMS finds the change is consistent with effective and efficient administration of the program and approves the request under paragraph (a) of this section, it will notify the provider, the outgoing intermediary, and the newly-elected intermediary (if any) that the change will be effective on the first day following the close of the fiscal year in which the request was filed.

[45 FR 42179, June 23, 1980, as amended at 49 FR 56036, Dec. 16, 1983; 49 FR 3660, Jan. 30, 1984]

§421.110 Requirements for approval of an agreement.

Before entering into or renewing an intermediary agreement, CMS will—

(a) Determine that to do so is consistent with the effective and efficient administration of the Medicare program;

(b) Review the performance of the intermediary as measured by the criteria (§421.120) and standards (§421.122); and

(c) Determine that the intermediary or prospective intermediary—

(1) Is willing and able to assist providers in the application of safeguards against unnecessary utilization of services;

(2) Meets all solvency and financial responsibility requirements imposed by the statutes and regulatory authorities of the State or States in which it, or any subcontractor performing some or all of its functions, would serve;

(3) Has the overall resources and experience to administer its responsibilities under the Medicare program and has an existing operational, statistical, and recordkeeping capacity to carry out the additional program responsibilities it proposes to assume. CMS will presume that an intermediary or prospective intermediary meets this requirement if it has at least 5 years experience in paying for or reimbursing the cost of health services;

(4) Will serve a sufficient number of providers to permit a finding of effective and efficient administration. Under this criterion no intermediary or prospective intermediary shall be found to be not efficient or effective solely on the grounds that it serves only providers located in a single State;

(5) Has acted in good faith to achieve effective cooperation with the providers it will service and with the physicians and medical societies in the area;

(6) Has established a record of integrity and satisfactory service to the public; and

(7) Has an affirmative equal employment opportunity program that complies with the fair employment provisions of the Civil Rights Act of 1964 and Executive Order 11246, as amended.

§ 421.112 Considerations relating to the effective and efficient administration of the program.

(a) In order to accomplish the most effective and efficient administration of the Medicare program, determinations may be made by the Secretary with respect to the termination of an intermediary agreement, or by CMS with respect to the—

(1) Renewal of an intermediary agreement (§ 421.110);

(2) Assignment or reassignment of providers to an intermediary (§ 421.114); or

(3) Designation of a regional or national intermediary to serve a class of providers (§ 421.116).

(b) When taking the actions listed in paragraph (a), the Secretary or CMS will consider the performance of the individual intermediary in its Medicare operations using the factors contained in the performance criteria (§ 421.120) and performance standards (§ 421.122).

(c) In addition, when taking the actions listed in paragraph (a) of this section, the Secretary or CMS may consider factors relating to—

(1) Consistency in the administration of program policy;

(2) Development of intermediary expertise in difficult areas of program administration;

(3) Individual capacity of available intermediaries to serve providers as it is affected by such considerations as—

(i) Program emphasis on the number or type of providers to be served; or

(ii) Changes in data processing technology;

(4) Overdependence of the program on the capacity of an intermediary to an extent that services could be interrupted;

(5) Economy in the delivery of intermediary services;

(6) Timeliness in the delivery of intermediary services;

(7) Duplication in the availability of intermediaries;

(8) Conflict of interest between an intermediary and provider; and

(9) Any additional pertinent factors.

[45 FR 42179, June 23, 1980, as amended at 59 FR 682, Jan. 6, 1994]

§ 421.114 Assignment and reassignment of providers by CMS.

CMS may assign or reassign any provider to any intermediary if it determines that the assignment or reassignment will result in a more effective and efficient administration of the Medicare program. Before making this determination CMS will consider—

(a) The preferences of the provider;

(b) The availability of an intermediary as specified in § 421.5(e); and

(c) Intermediary performance measured against the criteria and standards specified in §§ 421.120 and 421.122.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

§ 421.116 Designation of national or regional intermediaries.

(a) After considering intermediary performance measured against the criteria and standards specified in §§ 421.120 and 421.122, CMS may designate a particular intermediary to serve a class of providers nationwide or in any geographic area it defines. CMS may make this designation if it determines that the designation will result in a greater degree of effectiveness and efficiency in the administration of the Medicare program than could be achieved by an assignment of providers to an intermediary preferred by the providers.

(b) No designation may be made until the affected providers and intermediaries are given an explanation and the intermediaries are advised of their right to a hearing and judicial review as specified in § 421.128. This provision does not apply to experimental contracts awarded under § 421.118.

(c) To designate an intermediary, CMS may establish classes of providers on the basis of—

(1) The type of provider, for example, hospital, skilled nursing facility, home health agency; or

(2) Common characteristics.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

§ 421.117 Designation of regional and alternative designated regional intermediaries for home health agencies and hospices.

(a) This section is based on section 1816(e)(4) of the Social Security Act, which requires the Secretary to designate regional intermediaries for home health agencies (HHAs) other than hospital-based HHAs but permits him or her to designate regional intermediaries for hospital-based HHAs only if the designation meets promulgated criteria concerning administrative efficiency and effectiveness; on section 1816(e)(5) of the Social Security Act, which requires the Secretary to designate intermediaries for hospices; and on section 1874 of the Act, which permits CMS to contract with any organization for the purpose of making payments to any provider that elects to receive payment directly from CMS.

(b) CMS applies the following criteria to determine whether the assignment of hospital-based HHAs to designated regional intermediaries will result in the more effective and efficient administration of the Medicare program:

(1) Uniform interpretation of Medicare rules;

(2) Expertise in bill processing;

(3) Control of administrative costs;

(4) Ease of communication of program policy and issues to affected providers;

(5) Ease of data collection;

(6) Ease of CMS's monitoring of intermediary performance; and

(7) Other criteria as the Secretary believes to be pertinent.

(c) Except as provided in paragraphs (e), (f), and (g) of this section, an HHA must receive payment through a regional intermediary designated by CMS.

(d) Except as provided in paragraphs (f) through (h) of this section, a hospice must receive payment for covered services furnished to Medicare beneficiaries through an intermediary designated by CMS.

(e) An HHA chain not desiring to receive payment from designated regional intermediaries may request service by one lead intermediary with the assistance of a local designated regional intermediary. Alternatively, the chain may request to be serviced by a single intermediary. A lead, local, or a single intermediary must be an organization that is a designated regional intermediary. Any request made under this paragraph is evaluated by CMS in accordance with the criteria contained at § 421.106 of this subpart.

(f) An HHA or hospice not wishing to receive payment from a regional intermediary designated under paragraph (c) or (d) of this section may submit a request to the CMS Regional Office to receive payment through an alternative regional intermediary designated by CMS.

(g) Except as provided in paragraph (h) of this section, any request that an HHA or hospice may make to change

from a designated regional intermediary to an alternative designated regional intermediary, in accordance with paragraph (f) of this section, is evaluated by CMS in accordance with the criteria set forth at § 421.106(b) of this subpart and must be filed within the timeframe established at § 421.106(a) of this subpart.

(h) *Exception:* An HHA or a hospice that, as of June 20, 1988 is receiving payment from a designated regional intermediary may, without regard to the limitations contained in § 421.106 of this subpart, continue to receive payment from that intermediary. It may do so even if that intermediary is not the designated regional intermediary or the alternative designated regional intermediary for the particular State in which the HHA or hospice is located.

[53 FR 17944, May 19, 1988]

§ 421.118 Awarding of experimental contracts.

Notwithstanding the provisions of §§ 421.103 and 421.104, CMS may award a fixed price or performance incentive contract under the experimental authority contained in 42 U.S.C. 1395b–1 for performance of any of the functions specified in § 421.100. Action taken by CMS under this paragraph is not subject to—

(a) The administrative and judicial review which would otherwise be available under § 421.128; or

(b) Performance criteria and performance standards review as provided for in §§ 421.120 and 421.122.

[45 FR 42179, June 23, 1980, as amended at 59 FR 682, Jan. 6, 1994]

§ 421.120 Performance criteria.

(a) *Application of performance criteria.* As part of the intermediary evaluations authorized by section 1816(f) of the Act, CMS periodically assesses the performance of intermediaries in their Medicare operations using performance criteria. The criteria measure and evaluate intermediary performance of functional responsibilities such as—

(1) Correct coverage and payment determinations;

(2) Responsiveness to beneficiary concerns; and

(3) Proper management of administrative funds.

(b) *Basis for criteria.* CMS will base the performance criteria on—

(1) Nationwide intermediary experience;

(2) Changes in intermediary operations due to fiscal constraints; and

(3) HFCA's objectives in achieving better performance.

(c) *Publication of criteria.* The development and revision of criteria for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, CMS will publish the performance criteria as a notice in the FEDERAL REGISTER.

[48 FR 7178, Feb. 18, 1983]

§ 421.122 Performance standards.

(a) *Development of standards.* In addition to the performance criteria (§ 421.120), CMS develops detailed performance standards for use in evaluating intermediary performance which may be based on historical performance, application of acceptable statistical measures of variation to nationwide intermediary experience during a base period, or changing program emphases or requirements. These standards are also developed considering intermediary experience and evaluate the specific requirements of each functional responsibility or criterion.

(b) *Factors beyond intermediary's control.* To identify measurable factors that significantly affect an intermediary's performance, but that are not within the intermediary's control, CMS will—

(1) Study the performance of intermediaries during the base period, and

(2) Consider the noncontrollable factors in developing performance standards.

(c) *Publication of standards.* The development and revision of standards for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance standards as part of the FEDERAL REGISTER notice describing the performance criteria issued under § 421.120(c). CMS may not necessarily

publish the criteria and standards every year. CMS interprets the statutory phrase ''before the beginning of each evaluation period'' as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the intermediaries for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

§ 421.124 Intermediary's failure to perform efficiently and effectively.

(a) Failure by an intermediary to meet, or to demonstrate the capacity to meet, the criteria or standards specified in §§ 421.120 and 421.122 may be grounds for adverse action by the Secretary or by CMS, such as reassignment of providers, offer of a short-term agreement, termination of a contract, or non-renewal of a contract. If an intermediary meets all criteria and standards in its overall performance, but does not meet them with respect to a specific provider or class of providers, CMS may reassign that provider or class of providers to another intermediary in accordance with § 421.114.

(b) In addition, notwithstanding whether an intermediary meets the criteria and standards, if the cost incurred by the intermediary to meet its contractual requirements exceeds the amount which CMS finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated intermediary, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

§ 421.126 Termination of agreements.

(a) *Termination by intermediary*. An intermediary may terminate its agreement at any time by—

(1) Giving written notice of its intention to CMS and to the providers it services at least 180 days before its intended termination date; and

(2) Giving public notice of its intention by publishing a statement of the effective date of termination at least 60 days before that date. Publication must be in a newspaper of general circulation in each community served by the intermediary.

(b) *Termination by the Secretary, and right of appeal*. (1) The Secretary may terminate an agreement if—

(i) The intermediary fails to comply with the requirements of this subpart;

(ii) The intermediary fails to meet the criteria or standards specified in §§ 421.120 and 421.122; or

(iii) CMS has reassigned, under § 421.114 or § 421.116, all of the providers assigned to the intermediary.

(2) If the Secretary decides to terminate an agreement, he or she will offer the intermediary an opportunity for a hearing, in accordance with § 421.128.

(3) If the intermediary does not request a hearing, or if the hearing decision affirms the Secretary's decision, the Secretary will provide reasonable notice of the effective date of termination to—

(i) The intermediary;

(ii) The providers served by the intermediary; and

(iii) The general public.

(4) The providers served by the intermediary will be given the opportunity to nominate another intermediary, in accordance with § 421.104.

§ 421.128 Intermediary's opportunity for hearing and right to judicial review.

(a) *Basis for appeal*. An intermediary adversely affected by any of the following actions shall be granted an opportunity for a hearing:

(1) Assignment or reassignment of providers to another intermediary.

(2) Designation of a national or regional intermediary to serve a class of providers.

(3) Termination of the agreement.

(b) *Request for hearing*. The intermediary shall file the request with CMS within 20 days from the date on the notice of intended action.

(c) *Hearing procedures*. The hearing officer shall be a representative of the Secretary and not otherwise a party to the initial administrative decision. The intermediary may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings at the hearing will be made and transcribed.

(d) *Judicial review*. An adverse hearing decision concerning action under paragraph (a)(1) or (a)(2) of this section is

subject to judicial review in accordance with 5 U.S.C. chapter 7.

(e) As specified in § 421.118, contracts awarded under the experimental authority of CMS are not subject to the provisions of this section.

(f) *Exception.* An intermediary adversely affected by the designation of a regional intermediary or an alternative regional intermediary for HHAs, or an intermediary for hospices, under § 421.117 of this subpart is not entitled to a hearing or judicial review concerning adverse effects caused by the designation of an intermediary.

[45 FR 42179, June 23, 1980, as amended at 47 FR 38540, Sept. 1, 1982; 49 FR 3660, Jan. 30, 1984; 53 FR 17945, May 19, 1988]

Subpart C—Carriers

§ 421.200 Carrier functions.

A contract between CMS and a carrier, other than a regional DMEPOS carrier, specifies the functions to be performed by the carrier which must include, but are not necessarily limited to, the following:

(a) *Coverage.* (1) The carrier ensures that payment is made only for services that are:

(i) Furnished to Medicare beneficiaries;

(ii) Covered under Medicare; and

(iii) In accordance with QIO determinations when they are services for which the QIO has assumed review responsibility under its contract with CMS.

(2) The carrier takes appropriate action to reject or adjust the claim if—

(i) The carrier or the QIO determines that the services furnished or proposed to be furnished were not reasonable, not medically necessary, or not furnished in the most appropriate setting;

(ii) The carrier determines that the claim does not properly reflect the kind and amount of services furnished.

(b) *Payment on a cost basis.* If payment is on a cost basis, the carrier must assure that payments are based on reasonable costs, as determined under part 413 of this chapter.

(c) *Payment on a charge basis.* If payment is on a charge basis, under part 405, subpart E of this chapter, the carrier must ensure that—

(1) Charges are reasonable and not higher than the charge for a comparable service furnished under comparable circumstances to the carrier's policy holders and subscribers; and

(2) The payment is based on one of the following—

(i) An itemized bill.

(ii) An assignment under the terms of which the reasonable charge is the full charge for the service, as specified in § 424.55 of this chapter.

(iii) If the beneficiary has died, the procedures set forth in §§ 424.62 and 424.64 of this chapter.

(d) *Fiscal management.* The carrier must receive, disburse, and account for funds in making payments under Medicare.

(e) *Provider audits.* The carrier must audit the records of providers to whom it makes Medicare Part B payments to assure that payments are made properly.

(f) *Utilization patterns.* (1) The carrier must have methods and procedures for identifying utilization patterns that deviate from professionally established norms and bring the deviant patterns to the attention of appropriate professional groups.

(2) The carrier must assist providers and other persons who furnish Medicare Part B services to—

(i) Develop procedures relating to utilization practices;

(ii) Make studies of the effectiveness of those procedures and devise methods to improve them;

(iii) Apply safeguards against unnecessary utilization of services; and

(iv) Develop procedures for utilization review, and establish groups to perform such reviews of providers to whom it makes Medicare Part B payments.

(g) *Information and reports.* The carrier must furnish to CMS any information and reports that CMS requests in order to carry out CMS's responsibilities in the administration of the Medicare program. The carrier must be responsive to requests for information from the public.

(h) *Maintenance and availability of records.* The carrier must maintain and make available to CMS the records necessary for verification of payments and for other related purposes.

(i) *Hearings to Part B beneficiaries.* (1) The carrier must provide an opportunity for a fair hearing if it denies the beneficiary's request for payment, does not act upon the request with reasonable promptness, or pays less than the amount claimed.

(2) The hearing procedures must be in accordance with part 405, subpart H, of this chapter (Review and Hearing Under the Supplementary Medical Insurance Program).

(j) *Other terms and conditions.* The carrier must comply with any other terms and conditions included in its contract.

[45 FR 42183, June 23, 1980; 45 FR 64913, Oct. 1, 1980, as amended at 49 FR 3660, Jan. 30, 1984; 49 FR 9174, Mar. 12, 1984; 51 FR 34833, Sept. 30, 1986; 51 FR 41350, Nov. 14, 1986; 51 FR 43198, Dec. 1, 1986; 52 FR 4499, Feb. 12, 1987; 53 FR 6648, Mar. 2, 1988; 54 FR 4027, Jan. 27, 1989; 57 FR 27307, June 18, 1992]

§ 421.201 Performance criteria and standards.

(a) *Application of performance criteria and standards.* As part of the carrier evaluations mandated by section 1842(b)(2) of the Act, CMS periodically assesses the performance of carriers in their Medicare operations using performance criteria and standards.

(1) The criteria measure and evaluate carrier performance of functional responsibilities such as—

(i) Accurate and timely payment determinations;

(ii) Responsiveness to beneficiary, physician, and supplier concerns; and

(iii) Proper management of administrative funds.

(2) The standards evaluate the specific requirements of each functional responsibility or criterion.

(b) *Basis for criteria and standards.* CMS bases the performance criteria and standards on—

(1) Nationwide carrier experience;

(2) Changes in carrier operations due to fiscal constraints; and

(3) CMS's objectives in achieving better performance.

(c) *Publication of criteria and standards.* Before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance criteria and standards as a notice in the FEDERAL REGISTER. CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase ''before the beginning of each evaluation period'' as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the carriers for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

§ 421.202 Requirements and conditions.

Before entering into or renewing a carrier contract, CMS determines that the carrier—

(a) Has the capacity to perform its contractual responsibilities effectively and efficiently;

(b) Has the financial responsibility and legal authority necessary to carry out its responsibilities; and

(c) Will be able to meet any other requirements CMS considers pertinent, and, if designated a regional DMEPOS carrier, any special requirements for regional carriers under § 421.210 of this subpart.

[45 FR 42179, June 23, 1980, as amended at 57 FR 27307, June 18, 1992]

§ 421.203 Carrier's failure to perform efficiently and effectively.

(a) Failure by a carrier to meet, or demonstrate the capacity to meet, the criteria and standards specified in § 421.201 may be grounds for adverse action by the Secretary, such as contract termination or non-renewal.

(b) Notwithstanding whether or not a carrier meets the criteria and standards specified in § 421.201, if the cost incurred by the carrier to meet its contractual requirements exceeds the amount that CMS finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated carrier, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

§ 421.205 Termination by the Secretary.

(a) *Cause for termination.* The Secretary may terminate a contract with

a carrier at any time if he or she determines that the carrier has failed substantially to carry out any material terms of the contract or has performed its function in a manner inconsistent with the effective and efficient administration of the Medicare Part B program.

(b) *Notice and opportunity for hearing.* Upon notification of the Secretary's intent to terminate the contract, the carrier may request a hearing within 20 days after the date on the notice of intent to terminate.

(c) *Hearing procedures.* The hearing procedures will be those specified in § 421.128(c).

§ 421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies.

(a) *Basis.* This section is based on sections 1834(a)(12) and 1834(h) of the Act, which authorize the Secretary to designate one carrier for one or more entire regions to process claims for durable medical equipment, prosthetic devices, prosthetics, orthotics, and other supplies (DMEPOS). This authority has been delegated to CMS.

(b) *Types of claims.* Claims for the following, except for items incident to a physician's professional service as defined in § 410.26, incident to a physician's service in a rural health clinic as defined in § 405.2413, or bundled into payment to a provider, ambulatory surgical center, or other facility, are processed by the designated carrier for its designated region and not by other carriers—

(1) Durable medical equipment (and related supplies) as defined in section 1861(n) of the Act;

(2) Prosthetic devices (and related supplies) as described in section 1861(s)(8) of the Act, (including intraocular lenses and parenteral and enteral nutrients, supplies, and equipment, when furnished under the prosthetic device benefit);

(3) Orthotics and prosthetics (and related supplies) as described in section 1861(s)(9);

(4) Home dialysis supplies and equipment as described in section 1861(s)(2)(F);

(5) Surgical dressings and other devices as described in section 1861(s)(5);

(6) Immunosuppressive drugs as described in section 1861(s)(2)(J); and

(7) Other items or services which are designated by CMS.

(c) *Region designation.* (1) The boundaries of the initial four regions for processing claims described in paragraph (b) of this section contain the following States and territories:

(i) Region A: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, and Delaware.

(ii) Region B: Maryland, the District of Columbia, Virginia, West Virginia, Ohio, Michigan, Indiana, Illinois, Wisconsin, and Minnesota.

(iii) Region C: North Carolina, South Carolina, Kentucky, Tennessee, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, Arkansas, Oklahoma, New Mexico, Colorado, Puerto Rico, and the Virgin Islands.

(iv) Region D: Alaska, Hawaii, American Samoa, Guam, the Northern Mariana Islands, California, Nevada, Arizona, Washington, Oregon, Montana, Idaho, Utah, Wyoming, North Dakota, South Dakota, Nebraska, Kansas, Iowa, and Missouri.

(2) CMS has the option to modify the number and boundaries of the regions established in paragraph (c)(1) of this section based on appropriate criteria and considerations, including the effect of the change on beneficiaries and DMEPOS suppliers. To announce changes, CMS publishes a notice in the FEDERAL REGISTER that delineates the regional boundary or boundaries changed, the States and territories affected, and supporting criteria or considerations.

(d) *Criteria for designating regional carriers.* CMS designates regional carriers to achieve a greater degree of effectiveness and efficiency in the administration of the Medicare program. In making this designation, CMS will award regional carrier contracts in accordance with applicable law and will consider some or all of the following criteria—

(1) Timeliness of claim processing;

(2) Cost per claim;

(3) Claim processing quality;

(4) Experience in claim processing, and in establishing local medical review policy; and

(5) Other criteria that CMS believes to be pertinent.

(e) *Carrier designation.* (1) Each carrier designated a regional carrier must process claims for items listed in paragraph (b) of this section for beneficiaries whose permanent residence is within that carrier's region as designated under paragraph (c) of this section. When processing the claims, the carrier must use the payment rates applicable for the State of residence of the beneficiary, including a qualified Railroad Retirement beneficiary. A beneficiary's permanent residence is the address at which he or she intends to spend 6 months or more of the calendar year.

(2) CMS notifies affected Medicare beneficiaries and suppliers when it designates a regional carrier (in accordance with paragraph (d) of this section) to process DMEPOS claims (as defined in paragraph (b) of this section) for all Medicare beneficiaries residing in their respective regions (as designated under paragraph (c) of this section).

(3) CMS may contract for the performance of National Supplier Clearinghouse functions through a contract amendment to one of the DME regional carrier contracts or through a contract amendment to any Medicare carrier contract under §421.200.

(4) CMS periodically recompetes the contracts for the DME regional carriers. CMS also periodically recompetes the National Supplier Clearinghouse function.

(f) *Collecting information of ownership.* Carriers designated as regional claims processors must obtain from each supplier of items listed in paragraph (b) of this section information concerning ownership and control as required by section 1124A of the Act and part 420 of this chapter, and certifications that supplier standards are met as required by part 424 of this chapter.

[57 FR 27307, June 18, 1992, as amended at 58 FR 60796, Nov. 18, 1993; 70 FR 9239, Feb. 25, 2005]

§421.212 Railroad Retirement Board contracts.

In accordance with this subpart C, the Railroad Retirement Board contracts with DMEPOS regional carriers designated by CMS, as set forth in §421.210(e)(2), for processing claims for Medicare-eligible Railroad Retirement beneficiaries, for the same contract period as the contracts entered into between CMS and the DMEPOS regional carriers.

[58 FR 60797, Nov. 18, 1993]

§421.214 Advance payments to suppliers furnishing items or services under Part B.

(a) *Scope and applicability.* This section provides for the following:

(1) Sets forth requirements and procedures for the issuance and recovery of advance payments to suppliers of Part B services and the rights and responsibilities of suppliers under the payment and recovery process.

(2) Does not limit CMS's right to recover unadjusted advance payment balances.

(3) Does not affect suppliers' appeal rights under part 405, subpart H of this chapter relating to substantive determinations on suppliers' claims.

(4) Does not apply to claims for Part B services furnished by suppliers that have in effect provider agreements under section 1866 of the Act and part 489 of this chapter, and are paid by intermediaries.

(b) *Definition.* As used in this section, *advance payment* means a conditional partial payment made by the carrier in response to a claim that it is unable to process within established time limits.

(c) *When advance payments may be made.* An advance payment may be made if all of the following conditions are met:

(1) The carrier is unable to process the claim timely.

(2) CMS determines that the prompt payment interest provision specified in section 1842(c) of the Act is insufficient to make a claimant whole.

(3) CMS approves, in writing to the carrier, the making of an advance payment by the carrier.

(d) *When advance payments are not made.* Advance payments are not made

to any supplier that meets any of the following conditions:

(1) Is delinquent in repaying a Medicare overpayment.

(2) Has been advised of being under active medical review or program integrity investigation.

(3) Has not submitted any claims.

(4) Has not accepted claims' assignments within the most recent 180-day period preceding the system malfunction.

(e) *Requirements for suppliers.* (1) Except as provided for in paragraph (g)(1) of this section, a supplier must request, in writing to the carrier, an advance payment for Part B services it furnished.

(2) A supplier must accept an advance payment as a conditional payment subject to adjustment, recoupment, or both, based on an eventual determination of the actual amount due on the claim and subject to the provisions of this section.

(f) *Requirements for carriers.* (1) A carrier must notify a supplier as soon as it is determined that payment will not be made in a timely manner, and an advance payment option is to be offered to the supplier.

(i) A carrier must calculate an advance payment for a particular claim at no more than 80 percent of the anticipated payment for that claim based upon the historical assigned claims payment data for claims paid the supplier.

(ii) ''Historical data'' are defined as a representative 90-day assigned claims payment trend within the most recent 180-day experience before the system malfunction.

(iii) Based on this amount and the number of claims pending for the supplier, the carrier must determine and issue advance payments.

(iv) If historical data are not available or if backlogged claims cannot be identified, the carrier must determine and issue advance payments based on some other methodology approved by CMS.

(v) Advance payments can be made no more frequently than once every 2 weeks to a supplier.

(2) Generally, a supplier will not receive advance payments for more assigned claims than were paid, on a daily average, for the 90-day period before the system malfunction.

(3) A carrier must recover an advance payment by applying it against the amount due on the claim on which the advance was made. If the advance payment exceeds the Medicare payment amount, the carrier must apply the unadjusted balance of the advance payment against future Medicare payments due the supplier.

(4) In accordance with CMS instructions, a carrier must maintain a financial system of data in accordance with the Statement of Federal Financial Accounting Standards for tracking each advance payment and its recoupment.

(g) *Requirements for CMS.* (1) In accordance with the provisions of this section, CMS may determine that circumstances warrant the issuance of advance payments to all affected suppliers furnishing Part B services. CMS may waive the requirement in paragraph (e)(1) of this section as part of that determination.

(2) If adjusting Medicare payments fails to recover an advance payment, CMS may authorize the use of any other recoupment method available (for example, lump sum repayment or an extended repayment schedule) including, upon written notice from the carrier to the supplier, converting any unpaid balances of advance payments to overpayments. Overpayments are recovered in accordance with part 401, subpart F of this chapter concerning claims collection and compromise and part 405, subpart C of this chapter concerning recovery of overpayments.

(h) *Prompt payment interest.* An advance payment is a ''payment'' under section 1842(c)(2)(C) of the Act for purposes of meeting the time limit for the payment of clean claims, to the extent of the advance payment.

(i) *Notice, review, and appeal rights.* (1) The decision to advance payments and the determination of the amount of any advance payment are committed to CMS's discretion and are not subject to review or appeal.

(2) The carrier must notify the supplier receiving an advance payment about the amounts advanced and recouped and how any Medicare payment amounts have been adjusted.

(3) The supplier may request an administrative review from the carrier if it believes the carrier's reconciliation of the amounts advanced and recouped is incorrectly computed. If a review is requested, the carrier must provide a written explanation of the adjustments.

(4) The review and explanation described in paragraph (i)(3) of this section is separate from a supplier's right to appeal the amount and computation of benefits paid on the claim, as provided at part 405, subpart H of this chapter. The carrier's reconciliation of amounts advanced and recouped is not an initial determination as defined at § 405.803 of this chapter, and any written explanation of a reconciliation is not subject to further administrative review.

[61 FR 49275, Sept. 19, 1996]

PART 422—MEDICARE ADVANTAGE PROGRAM

Subpart A—General Provisions

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 63 FR 18134, Apr. 14, 1998, unless otherwise noted.

EDITORIAL NOTE; Nomenclature changes to part 422 appear at 70 FR 4741, Jan. 28, 2005.

Subpart A—General Provisions

SOURCE: 63 FR 35068, June 26, 1998, unless otherwise noted.

§ 422.1 Basis and scope.

(a) *Basis*. This part is based on the indicated provisions of the following sections of the Act:

1851—Eligibility, election, and enrollment.
1852—Benefits and beneficiary protections.
1853—Payments to Medicare Advantage (MA) organizations.
1854—Premiums.
1855—Organization, licensure, and solvency of MA organizations.
1856—Standards.
1857—Contract requirements.
1858—Special rules for MA Regional Plans.
1859—Definitions; enrollment restriction for certain MA plans.

(b) *Scope*. This part establishes standards and sets forth the requirements, limitations, and procedures for Medicare services furnished, or paid for, by Medicare Advantage organizations through Medicare Advantage plans.

[63 FR 35068, June 26, 1998, as amended at 70 FR 4714, Jan. 28, 2005]

§ 422.2 Definitions.

As used in this part—

Arrangement means a written agreement between an MA organization and a provider or provider network, under which—

(1) The provider or provider network agrees to furnish for a specific MA plan(s) specified services to the organization's MA enrollees;

(2) The organization retains responsibilities for the services; and

(3) Medicare payment to the organization discharges the enrollee's obligation to pay for the services.

Balance billing generally refers to an amount billed by a provider that represents the difference between the amount the provider charges an individual for a service and the sum of the amount the individual's health insurer (for example, the original Medicare program) will pay for the service plus any cost-sharing by the individual.

Basic benefits means all Medicare-covered benefits (except hospice services).

Benefits means health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.

Coinsurance is a fixed percentage of the total amount paid for a health care service that can be charged to an MA enrollee on a per-service basis.

Copayment is a fixed amount that can be charged to an MA plan enrollee on a per-service basis.

Cost-sharing includes deductibles, coinsurance, and copayments.

Institutionalized means for the purpose of defining a special needs individual, an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care facility which is a skilled nursing facility (SNF) nursing facility (NF); SNF/NF; an intermediate care facility for the mentally retarded (ICF/MR); or an inpatient psychiatric facility.

Licensed by the State as a risk-bearing entity means the entity is licensed or otherwise authorized by the State to assume risk for offering health insurance or health benefits coverage, such that the entity is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health services under an MA contract.

MA stands for Medicare Advantage.

MA local area is defined in § 422.252.

MA local plan means an MA plan that is not an MA regional plan.

MA-Prescription drug (PD) plan means an MA plan that provides qualified prescription drug coverage under Part D of the Social Security Act.

MA regional plan means a coordinated care plan structured as a preferred provider organization (PPO) that serves one or more entire regions. An MA regional plan must have a network of contracting providers that have agreed to a specific reimbursement for the plan's covered services and must pay for all covered services whether provided in or out of the network.

MA eligible individual means an individual who meets the requirements of § 422.50.

MA organization means a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements.

MA plan means health benefits coverage offered under a policy or contract by an MA organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan (or in individual segments of a service area, under § 422.304(b)(2)).

MA plan enrollee is an MA eligible individual who has elected an MA plan offered by an MA organization.

Mandatory supplemental benefits means health care services not covered by Medicare that an MA enrollee must accept or purchase as part of an MA plan. The benefits may include reductions in cost sharing for benefits under the original Medicare fee for service program and are paid for in the form of premiums and cost sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

MSA stands for medical savings account.

MSA trustee means a person or business with which an enrollee establishes an MA MSA. A trustee may be a bank, an insurance company, or any other entity that—

(1) Is approved by the Internal Revenue Service to be a trustee or custodian of an individual retirement account (IRA); and

(2) Meets the requirements of § 422.262(b).

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service that CMS makes under section 1862(a)(1) of the Act, and publishes as a FEDERAL REGISTER notice or CMS ruling. (The term does not include coverage changes mandated by statute.)

Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

Original Medicare means health insurance available under Medicare Part A and Part B through the traditional fee-for service payment system.

Point of service (POS) is a benefit option that an MA coordinated care plan can offer to its Medicare enrollees as an additional, mandatory supplemental, or optional supplemental benefit. Under the POS benefit option, the MA plan allows members the option of receiving specified services outside of the MA plan's provider network. In return for this flexibility, members typically have higher cost-sharing requirements for services received and, where offered as a mandatory or optional supplemental benefit, may also be charged a premium for the POS benefit option.

Prescription drug plan (PDP). PDP has the definition set forth in § 423.4 of this chapter.

Prescription drug plan (PDP) sponsor. A prescription drug plan sponsor has the definition set forth in § 423.4 of this chapter.

Provider means—

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation.

Provider network means the providers with which an MA organization contracts or makes arrangements to furnish covered health care services to Medicare enrollees under an MA coordinated care plan.

Religious Fraternal benefit (RFB) society means an organization that—

(1) Is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act; and

(2) Is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches.

RFB plan means an MA plan that is offered by an RFB society.

Service area means a geographic area that for local MA plans is a county or multiple counties, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

(1) For local MA plans:

(i) Whether the area meets the ''county integrity rule'' that a service area generally consists of a full county or counties.

(ii) However, CMS may approve a service area that includes only a portion of a county if it determines that the ''partial county'' area is necessary, nondiscriminatory, and in the best interests of the beneficiaries. CMS may also consider the extent to which the proposed service area mirrors service areas of existing commercial health care plans or MA plans offered by the organization.

(2) For all MA coordinated care plans, whether the contracting provider network meets the access and

availability standards set forth in § 422.112. Although not all contracting providers must be located within the plan's service area, CMS must determine that all services covered under the plan are accessible from the service area.

(3) For MA regional plans, whether the service area consists of the entire region.

Special needs individual means an MA eligible individual who is institutionalized, as defined above, is entitled to medical assistance under a State plan under title XIX, or has a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan.

Specialized MA Plans for Special Needs Individuals means a MA coordinated care plan that exclusively enrolls or enrolls a disproportionate percentage of special needs individuals as set forth in § 422.4(a)(1)(iv) and that, beginning January 1, 2006, provides Part D benefits under part 423 of this chapter to all enrollees; and which has been designated by CMS as meeting the requirements of a MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4714, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.4 Types of MA plans.

(a) *General rule.* An MA plan may be a coordinated care plan, a combination of an MA MSA plan and a contribution into an MA MSA established in accordance with § 422.262, or an MA private fee-for-service plan.

(1) *A coordinated care plan.* A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by CMS.

(i) The network is approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(ii) Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care.

(iii) Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), regional or local preferred provider organizations (PPOs) as specified in paragraph (a)(1)(v) of this section, and other network plans (except PFFS plans).

(iv) A specialized MA plan for special needs individuals (SNP) includes any type of coordinated care plan that meets CMS'SNP requirements and either—

(A) Exclusively enrolls special needs individuals as defined in § 422.2; or

(B) Enrolls a greater proportion of special needs individuals than occur nationally in the Medicare population as defined by CMS.

(v) A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and, only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO.

(2) *A combination of an MA MSA plan and a contribution into the MA MSA established in accordance with § 422.262.* (i) *MA MSA plan* means a plan that—

(A) Pays at least for the services described in § 422.101, after the enrollee has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in § 422.103(d); and

(B) Meets all other applicable requirements of this part.

(ii) *MA MSA* means a trust or custodial account—

(A) That is established in conjunction with an MSA plan for the purpose of paying the qualified expenses of the account holder; and

(B) Into which no deposits are made other than contributions by CMS under the MA program, or a trustee-to-trustee transfer or rollover from another MA MSA of the same account holder, in accordance with the requirements of sections 138 and 220 of the Internal Revenue Code.

(3) *MA private fee-for-service plan.* An MA private fee-for-service plan is an MA plan that—

(i) Pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(ii) Does not vary the rates for a provider based on the utilization of that provider's services; and

(iii) Does not restrict enrollees' choices among providers that are lawfully authorized to provide services and agree to accept the plan's terms and conditions of payment.

(b) *Multiple plans.* Under its contract, an MA organization may offer multiple plans, regardless of type, provided that the MA organization is licensed or approved under State law to provide those types of plans (or, in the case of a PSO plan, has received from CMS a waiver of the State licensing requirement). If an MA organization has received a waiver for the licensing requirement to offer a PSO plan, that waiver does not apply to the licensing requirement for any other type of MA plan.

(c) *Rule for MA Plans' Part D coverage.*

(1) Coordinated care plans. In order to offer an MA coordinated care plan in an area, the MA organization offering the coordinated care plan must offer qualified Part D coverage meeting the requirements in § 423.104 of this chapter in that plan or in another MA plan in the same area.

(2) *MSAs.* MA organizations offering MSA plans are not permitted to offer prescription drug coverage, other than that required under Parts A and B of Title XVIII of the Act.

(3) *Private Fee-For-Service.* MA organizations offering private fee-for-service plans can choose to offer qualified Part D coverage meeting the requirements in § 423.104 in that plan.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40315, June 29, 2000; 70 FR 4714, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.6 Cost-sharing in enrollment-related costs.

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that CMS follows to determine the aggregate annual ''user fee'' to be contributed by MA organizations and PDP sponsors under Medicare Part D and to assess the required user fees for each MA plan offered by MA organizations and PDP sponsors.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes CMS to charge and collect from each MA plan offered by an MA organization its pro rata share of fees for administering section 1851 of the Act (relating to dissemination of enrollment information), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program) and section 1860D–1(c) of the Act (relating to dissemination of enrollment information for the drug benefit).

(c) *Applicability.* The fee assessment also applies to those demonstrations for which enrollment is effected or coordinated under section 1851 of the Act.

(d) *Collection of fees.* (1) *Timing of collection.* CMS collects the fees over 9 consecutive months beginning with January of each fiscal year.

(2) *Amount to be collected.* The aggregate amount of fees for a fiscal year is the lesser of—

(i) The estimated costs to be incurred by CMS in that fiscal year to carry out the activities described in paragraph (b) of this section; or

(ii) For fiscal year 2006 and each succeeding year, the applicable portion (as defined in paragraph (e) of this section) of $200 million.''

(e) *Applicable portion.* In this section, the term ''applicable portion'' with respect to an MA plan means, for a fiscal year, CMS's estimate of Medicare Part C and D expenditures for those MA organizations as a percentage of all expenditures under title XVIII and with respect to PDP sponsors, the applicable portion is CMS's estimate of Medicare Part D prescription drug expenditures for those PDP sponsors as a percentage of all expenditures under title XVIII.

(f) *Assessment methodology.* (1) The amount of the applicable portion of the user fee each MA organization and PDP sponsor must pay is assessed as a percentage of the total Medicare payments to each organization. CMS determines the annual assessment percentage rate separately for MA organizations and for PDPs using the following formula:

(i) The assessment formula for MA organizations (including MA-PD plans):

C divided by A times B where—

A is the total estimated January payments to all MA organizations subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year MA organization user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(ii) The assessment formula for PDPs: C divided by A times B where—A is the total estimated January payments to all PDP sponsors subject to the assessment; B is the 9-month (January through September) assessment period; and C is the total fiscal year PDP sponsor's user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) CMS determines each MA organization's and PDP sponsor's pro rata share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. CMS calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in CMS's payment system on the first day of the month.

(3) CMS deducts the organization's fee from the amount of Federal funds otherwise payable to the MA organization or PDP sponsor for that month.

(4) If assessments reach the amount authorized for the year before the end of September, CMS discontinues assessment.

(5) If there are delays in determining the amount of the annual aggregate fees specified in paragraph (d)(2) of this section, or the fee percentage rate specified in paragraph (f)(2), CMS may adjust the assessment time period and the fee percentage amount.

[65 FR 40315, June 29, 2000. Redesignated and amended at 70 FR 4715, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

Subpart B—Eligibility, Election, and Enrollment

SOURCE: 63 FR 35071, June 26, 1998, unless otherwise noted.

§ 422.50 Eligibility to elect an MA plan.

For this subpart, all references to an MA plan include MA-PD and both MA local and MA regional plans, as defined in § 422.2 unless specifically noted otherwise.

(a) An individual is eligible to elect an MA plan if he or she—

(1) Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or CMP with a risk contract under part 417 of this chapter on December 31, 1998 may continue to be enrolled in the MA organization as an MA plan enrollee);

(2) Has not been medically determined to have end-stage renal disease, except that—

(i) An individual who develops end-stage renal disease while enrolled in an MA plan or in a health plan offered by the MA organization is eligible to elect an MA plan offered by that organization;

(ii) An individual with end-stage renal disease whose enrollment in an MA plan was terminated or discontinued after December 31, 1998, because CMS or the MA organization terminated the MA organization's contract for the plan or discontinued the plan in the area in which the individual resides, is eligible to elect another MA plan. If the plan so elected is later terminated or discontinued in the area in which the individual resides, he or she may elect another MA plan; and

(iii) An individual with end-stage renal disease may elect an MA special needs plan as defined in § 422.2, as long as that plan has opted to enroll ESRD individuals.

(3) Meets either of the following residency requirements:

(i) Resides in the service area of the MA plan.

(ii) Resides outside of the service area of the MA plan and is enrolled in a health plan offered by the MA organization during the month immediately preceding the month in which the individual is entitled to both Medicare Part A and Part B, provided that an MA organization chooses to offer this option and that CMS determines that all applicable MA access requirements of § 422.112 are met for that individual through the MA plan's established provider network. The MA organization must furnish the same benefits to these enrollees as to enrollees who reside in the service area;

(4) Has been a member of an Employer Group Health Plan (EGHP) that includes the elected MA plan, even if the individual lives outside of the MA plan service area, provided that an MA organization chooses to offer this option and that CMS determines that all applicable MA access requirements at § 422.112 are met for that individual through the MA plan's established provider network. The MA organization must furnish the same benefits to all enrollees, regardless of whether they reside in the service area;

(5) Completes and signs an election form or completes another CMS-approved election method offered by the MA organization and provides information required for enrollment; and

(6) Agrees to abide by the rules of the MA organization after they are disclosed to him or her in connection with the election process.

(b) An MA eligible individual may not be enrolled in more than one MA plan at any given time.

[63 FR 35071, June 26, 1998; 63 FR 52611, Oct. 1, 1998, as amended at 65 FR 40316, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4715, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

(a) *General rule*. In order to elect a specialized MA plan for a special needs individual (Special Needs MA plan, or SNP), the individual must meet the eligibility requirements specified in this section.

(b) *Basic eligibility requirements*. Except as provided in paragraph (c) of this section, to be eligible to elect an SNP, an individual must:

(1) Meet the definition of a special needs individual, as defined at § 422.2;

(2) Meet the eligibility requirements for that specific SNP; and

(3) Be eligible to elect an MA plan under § 422.50.

(c) *Exception to § 422.50*. CMS may waive § 422.50(a)(2) concerning the exclusion of persons with ESRD.

(d) *Deeming continued eligibility*. If an SNP determines that the enrollee no longer meets the eligibility criteria, but can reasonably be expected to again meet that criteria within a 6-month period, the enrollee is deemed to continue to be eligible for the MA plan for a period of not less than 30 days but not to exceed 6 months.

(e) *Restricting Enrollment*. An SNP must restrict future enrollment to only special needs individuals as established under § 422.2.

(f) *Exceptions*. (1) As specified in § 422.4, CMS may designate certain MA plans that disproportionately serve special needs individuals, as defined in § 422.2 as SNPs.

(2) Individuals already enrolled in an MA plan that CMS subsequently designates as an SNP may continue to be enrolled in the plan and may not be involuntarily disenrolled because they do not meet the definition of special needs individuals in § 422.2.

[70 FR 4716, Jan. 28, 2005]

§ 422.54 Continuation of enrollment for MA local plans.

(a) *Definition*. *Continuation area* means an additional area (outside the service area) within which the MA organization offering a local plan furnishes or arranges to furnish services to its continuation-of-enrollment enrollees. Enrollees must reside in a continuation area on a permanent basis. A continuation area does not expand the service area of any MA local plan.

(b) *Basic rule*. An MA organization may offer a continuation of enrollment option to MA local plan enrollees when they no longer reside in the service area of a plan and permanently move into the geographic area designated by the MA organization as a continuation area. The intent to no longer reside in

an area and permanently live in another area is verified through documentation that establishes residency, such as a driver's license or voter registration card.

(c) *General requirements.* (1) An MA organization that wishes to offer a continuation of enrollment option must meet the following requirements:

(i) Obtain CMS's approval of the continuation area, the marketing materials that describe the option, and the MA organization's assurances of access to services.

(ii) Describe the option(s) in the member materials it offers and make the option available to all MA local plan enrollees residing in the continuation area.

(2) An enrollee who moves out of the service area and into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the MA local plan. The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

(d) *Specific requirements*—

(1) *Continuation of enrollment benefits.* The MA organization must, at a minimum, provide or arrange for the Medicare-covered benefits as described in § 422.101(a).

(2) *Reasonable access.* The MA organization must ensure reasonable access in the continuation area—

(i) Through contracts with providers, or through direct payment of claims that satisfy the requirements in § 422.100(b)(2), to other providers who meet the requirement in subpart E of this part; and

(ii) By ensuring that the access requirements of § 422.112 are met.

(3) Reasonable cost sharing. For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the MA local plan's service area (in which the enrollee no longer resides).

(4) *Protection of enrollee rights.* An MA organization that offers a continuation of enrollment option must convey all enrollee rights conferred under this rule, with the understanding that—

(i) The ultimate responsibility for all appeals and grievance requirements remain with the organization that is receiving payment from CMS; and

(ii) Organizations that require enrollees to give advance notice of intent to use the continuation of enrollment option, must stipulate the notification process in the marketing materials.

(e) *Capitation payments.* CMS's capitation payments to all MA organizations, for all Medicare enrollees, are based on rates established on the basis of the enrollee's permanent residence, regardless of where he or she receives services.

[63 FR 35071, June 26, 1998; 63 FR 52611, Oct. 1, 1998, as amended at 65 FR 40316, June 29, 2000; 70 FR 4716, Jan. 28, 2005]

§ 422.56 Enrollment in an MA MSA plan.

(a) *General.* An individual is not eligible to elect an MA MSA plan unless the individual provides assurances that are satisfactory to CMS that he or she will reside in the United States for at least 183 days during the year for which the election is effective.

(b) *Individuals eligible for or covered under other health benefits program.* Unless otherwise provided by the Secretary, an individual who is enrolled in a Federal Employee Health Benefit plan under 5 U.S.C. chapter 89, or is eligible for health care benefits through the Veteran's Administration under 10 U.S.C. chapter 55 or the Department of Defense under 38 U.S.C. chapter 17, may not enroll in an MA MSA plan.

(c) *Individuals eligible for Medicare cost-sharing under Medicaid State plans.* An individual who is entitled to coverage of Medicare cost-sharing under a State plan under title XIX of the Act is not eligible to enroll in an MA MSA plan.

(d) *Other limitations.* An individual who receives health benefits that cover all or part of the annual deductible under the MA MSA plan may not enroll in an MA MSA plan. Examples of this type of coverage include, but are not limited to, primary health care coverage other than Medicare, current coverage under the Medicare hospice benefit, supplemental insurance policies not specifically permitted under

§ 422.104, and retirement health benefits.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 70 FR 4716, Jan. 28, 2005]

§ 422.57 Limited enrollment under MA RFB plans.

An RFB society that offers an MA RFB plan may offer that plan only to members of the church, or convention or group of churches with which the society is affiliated.

§ 422.60 Election process.

(a) *Acceptance of enrollees: General rule.* (1) Except for the limitations on enrollment in an MA MSA plan provided by § 422.62(d)(1) and except as specified in paragraph (a)(2) of this section, each MA organization must accept without restriction (except for an MA RFB plan as provided by § 422.57) individuals who are eligible to elect an MA plan that the MA organization offers and who elect an MA plan during initial coverage election periods under § 422.62(a)(1), annual election periods under § 422.62(a)(2), and under the circumstances described in § 422.62(b)(1) through (b)(4).

(2) MA organizations must accept elections during the open enrollment periods specified in § 422.62(a)(3), (a)(4), and (a)(5) if their MA plans are open to new enrollees.

(b) *Capacity to accept new enrollees.* (1) MA organizations may submit information on enrollment capacity of plans.

(2) If CMS determines that an MA plan offered by an MA organization has a capacity limit, and the number of MA eligible individuals who elect to enroll in that plan exceeds the limit, the MA organization offering the plan may limit enrollment in the plan under this part, but only if it provides priority in acceptance as follows:

(i) First, for individuals who elected the plan prior to the CMS determination that capacity has been exceeded, elections will be processed in chronological order by date of receipt of their election forms.

(ii) Then for other individuals in a manner that does not discriminate on the basis of any factor related to health as described in § 422.110.

(3) CMS considers enrollment limit requests for an MA plan service area, or a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

(c) *Election forms and other election mechanisms.* (1) The election must comply with CMS instructions regarding content and format and be approved by CMS as described in § 422.80. The election must be completed by the MA eligible individual (or the individual who will soon become eligible to elect an MA plan) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the MA organization. Persons who assist beneficiaries in completing forms must sign the form, or through other approved mechanisms, indicate their relationship to the beneficiary.

(2) The MA organization must file and retain election forms for the period specified in CMS instructions.

(d) *When an election is considered to have been made.* An election in an MA plan is considered to have been made on the date the completed election is received by the MA organization.

(e) *Handling of elections.* The MA organization must have an effective system for receiving, controlling, and processing elections. The system must meet the following conditions and requirements:

(1) Each election is dated as of the day it is received in a manner acceptable to CMS.

(2) Elections are processed in chronological order, by date of receipt.

(3) The MA organization gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) If the MA plan is enrolled to capacity, it explains the procedures that will be followed when vacancies occur.

(5) Upon receipt of the election, or for an individual who was accepted for future enrollment from the date a vacancy occurs, the MA organization transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary

to its records as an enrollee of the MA organization.

(f) *Exception for employer group health plans.* (1) In cases in which an MA organization has both a Medicare contract and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process elections for Medicare-entitled group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.308(f)(2), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) In order to obtain the effective date described in paragraph (f)(1) of this section, the beneficiary must certify that, at the time of enrollment in the MA organization, he or she received the disclosure statement specified in § 422.111.

(3) Upon receipt of the election from the employer, the MA organization must submit the enrollment within timeframes specified by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998; 63 FR 54526, Oct. 9, 1998; 64 FR 7980, Feb. 17, 1999; 65 FR 40316, June 29, 2000; 70 FR 4716, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.62 Election of coverage under an MA plan.

(a) *General: Coverage election periods*—(1) *Initial coverage election period for MA.* The initial coverage election period is the period during which a newly MA-eligible individual may make an initial election. This period begins 3 months before the month the individual is first entitled to both Part A and Part B and ends on the later of—

(i) The last day of the month preceding the month of entitlement; or

(ii) If after May 15, 2006, the last day of the individual's Part B initial enrollment period.

(2) *Annual coordinated election period.* (i) Beginning with 2002, the annual coordinated election period for the following calendar year is November 15th through December 31st, except for 2006.

(ii) For 2006, the annual coordinated election period

begins on November 15, 2005 and ends on May 15, 2006.

(iii) During the annual coordinated election period, an individual eligible to enroll in an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan. If an individual changes his or her election to original Medicare, he or she may also elect a PDP.

(3) *Open enrollment and disenrollment opportunities through 2005.* Through 2005, the number of elections or changes that an MA eligible individual may make is not limited (except as provided for in paragraph (d) of this section for MA MSA plans). Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an individual eligible to elect an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan.

(4) *Open enrollment and disenrollment during 2006.* (i) Except as provided in paragraphs (a)(4)(ii), (a)(4)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan, but who is eligible to elect an MA plan in 2006, may elect an MA plan only once during the first 6 months of the year.

(A) An individual who is enrolled in an MA-PD plan may elect another MA-PD plan or original Medicare and coverage under a PDP. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. Such an individual may not elect an MA-PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible during 2006 may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 6th month of the entitlement, or on December 31, whichever is earlier, subject to the limitations in paragraphs (a)(4)(i)(A) and (a)(4)(i)(B) of this section.

(iii) The limitation to one election or change in paragraphs (a)(4)(i) and (a)(4)(ii) of this section does not apply

to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(5) *Open enrollment and disenrollment beginning in 2007.* (i) For 2007 and subsequent years, except as provided in paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan but is eligible to elect an MA plan may make an election into an MA plan once during the first 3 months of the year.

(A) An individual who is enrolled in an MA-PD plan may elect another MA-PD plan or original Medicare and coverage under a PDP. An individual who is in original Medicare and has coverage under a PDP may elect a MA-PD plan. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. An individual who is in original Medicare and does not have coverage under a PDP may elect an MA plan that does not provide qualified prescription drug coverage. Such an individual may not elect an MA-PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible during 2007 or later may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 3rd month of the entitlement, or on December 31, whichever is earlier subject to the limitations in paragraphs (a)(5)(i)(A) and (a)(5)(i)(B) of this section.

(iii) The limitation to one election or change in paragraph (a)(5)(i) and (a)(5)(ii) of this section does not apply to elections made or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(6) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to elect an MA plan and who is institutionalized, as defined by CMS, is not limited (except as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make. Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to original Medicare, to a different MA plan, or from original Medicare to an MA plan.

(b) *Special election periods.* An individual may at any time (that is, not limited to the annual coordinated election period) discontinue the election of an MA plan offered by an MA organization and change his or her election, in the form and manner specified by CMS, from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

(1) CMS or the organization has terminated the organization's contract for the plan, discontinued the plan in the area in which the individual resides, or the organization has notified the individual of the impending termination of the plan, or the impending discontinuation of the plan in the area in which the individual resides.

(2) The individual is not eligible to remain enrolled in the plan because of a change in his or her place of residence to a location out of the service area or continuation area or other change in circumstances as determined by CMS but not including terminations resulting from a failure to make timely payment of an MA monthly or supplemental beneficiary premium, or from disruptive behavior.

(3) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The organization offering the plan substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following:

(A) Failure to provide the beneficiary on a timely basis medically necessary services for which benefits are available under the plan.

(B) Failure to provide medical services in accordance with applicable quality standards; or

(ii) The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(4) The individual meets such other exceptional conditions as CMS may provide.

(c) *Special election period for individual age 65.* Effective January 1, 2002, an MA eligible individual who elects an MA plan during the initial enrollment period, as defined under section 1837(d) of the Act, that surrounds his or her 65th birthday (this period begins 3 months before and ends 3 months after the month of the individual's 65th birthday) may discontinue the election of that plan and elect coverage under original Medicare at any time during the 12-month period that begins on the effective date of enrollment in the MA plan.

(d) *Special rules for MA MSA plans*—(1) *Enrollment.* An individual may enroll in an MA MSA plan only during an initial coverage election period or annual coordinated election period described in paragraphs (a)(1) and (a)(2) of this section.

(2) *Disenrollment.* (i) Except as provided in paragraph (d)(2)(ii) of this section, an individual may disenroll from an MA MSA plan only during—

(A) An annual election period; or

(B) The special election period described in paragraph (b) of this section.

(ii) *Exception.* An individual who elects an MA MSA plan during an annual election period and has never before elected an MA MSA plan may revoke that election, no later than December 15 of that same year, by submitting to the organization that offers the MA MSA plan a signed and dated request in the form and manner prescribed by CMS or by filing the appropriate disenrollment form through other mechanisms as determined by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40317, June 29, 2000; 70 FR 4717, Jan. 28, 2005]

§ 422.64 Information about the MA program.

Each MA organization must provide, on an annual basis, and in a format and using standard terminology that may be specified by CMS, the information necessary to enable CMS to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage.

[65 FR 40317, June 29, 2000]

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

(a) *Enrollment.* An individual who wishes to elect an MA plan offered by an MA organization may make or change his or her election during the election periods specified in § 422.62 by filing the appropriate election form with the organization or through other mechanisms as determined by CMS.

(b) *Disenrollment*—(1) *Basic rule.* An individual who wishes to disenroll from an MA plan may change his or her election during the election periods specified in § 422.62 in either of the following manners:

(i) Elect a different MA plan by filing the appropriate election with the MA organization.

(ii) Submit a request for disenrollment to the MA organization in the form and manner prescribed by CMS or file the appropriate disenrollment request through other mechanisms as determined by CMS.

(2) *When a disenrollment request is considered to have been made.* A disenrollment request is considered to have been made on the date the disenrollment request is received by the MA organization.

(3) *Responsibilities of the MA organization.* The MA organization must—

(i) Submit a disenrollment notice to CMS within timeframes specified by CMS;

(ii) Provide enrollee with notice of disenrollment in a format specified by CMS; and

(iii) In the case of a plan where lock-in applies, include in the notice a statement explaining that he or she—

(A) Remains enrolled until the effective date of disenrollment; and

(B) Until that date, neither the MA organization nor CMS pays for services not provided or arranged for by the MA plan in which the enrollee is enrolled; and

(iv) File and retain disenrollment requests for the period specified in CMS instructions.

(4) *Effect of failure to submit disenrollment notice to CMS promptly.* If the MA organization fails to submit the correct and complete notice required in paragraph (b)(3)(i) of this section, the MA organization must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

(5) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(i) There never was a legally valid enrollment.

(ii) A valid request for disenrollment was properly made but not processed or acted upon.

(c) *Election by default: Initial coverage election period.* An individual who fails to make an election during the initial coverage election period is deemed to have elected original Medicare.

(d) *Conversion of enrollment (seamless continuation of coverage)*—(1) *Basic rule.* An MA plan offered by an MA organization must accept any individual (regardless of whether the individual has end-stage renal disease) who is enrolled in a health plan offered by the MA organization during the month immediately preceding the month in which he or she is entitled to both Part A and Part B, and who meets the eligibility requirements at § 422.50.

(2) *Reserved vacancies.* Subject to CMS's approval, an MA organization may set aside a reasonable number of vacancies in order to accommodate enrollment of conversions. Any set aside vacancies that are not filled within a reasonable time must be made available to other MA eligible individuals.

(3) *Effective date of conversion.* If an individual chooses to remain enrolled with the MA organization as an MA enrollee, the individual's conversion to an MA enrollee is effective the month in which he or she is entitled to both Part A and Part B in accordance with the requirements in paragraph (d)(5) of this section.

(4) *Prohibition against disenrollment.* The MA organization may disenroll an individual who is converting under the provisions of paragraph (a) of this section only under the conditions specified in § 422.74.

(5) *Election.* The individual who is converting must complete an election as described in § 422.60(c)(1) unless otherwise provided in a form and manner approved by CMS.

(6) *Submittal of information to CMS.* The MA organization must transmit the information necessary for CMS to add the individual to its records as specified in § 422.60(e)(6).

(e) *Maintenance of enrollment.* (1) An individual who has made an election under this section is considered to have continued to have made that election until either of the following, which ever occurs first:

(i) The individual changes the election under this section.

(ii) The elected MA plan is discontinued or no longer serves the area in which the individual resides, as provided under § 422.74(b)(3), or the organization does not offer or the individual does not elect the option of continuing enrollment, as provided under § 422.54.

(2) An individual enrolled in an MA plan that becomes an MA-PD plan on January 1, 2006, will be deemed to have elected to enroll in that MA-PD plan.

(3) An individual enrolled in an MA plan that, as of

December 31, 2005, offers any prescription drug coverage will be deemed to have elected an MA-PD plan offered by the same organization as of January 1, 2006.

(4) An individual who has elected an MA plan that does not provide prescription drug coverage will not be deemed to have elected an MA-PD plan and will remain enrolled in the MA plan as provided in paragraph (e)(1) of this section.

(5) An individual enrolled in an MA-PD plan as of December 31 of a year is deemed to have elected to remain enrolled in that plan on January 1 of the following year.

(f) *Exception for employer group health plans.* (1) In cases when an MA organization has both a Medicare contract

and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process election forms for Medicare-entitled group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.308(f)(2), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election from the employer, the MA organization must submit a disenrollment notice to CMS within timeframes specified by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40317, June 29, 2000; 70 FR 4718, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.68 Effective dates of coverage and change of coverage.

(a) *Initial coverage election period.* An election made during an initial coverage election period as described in § 422.62(a)(1) is effective as of the first day of the month of entitlement to both Part A and Part B.

(b) *Annual coordinated election periods.* For an election or change of election made during the annual coordinated election period as described in § 422.62(a)(2)(i), coverage is effective as of the first day of the following calendar year except that for the annual coordinated election period described in § 422.62(a)(2)(ii), elections made after December 31, 2005 through May 15, 2006 are effective as of the first day of the first calendar month following the month in which the election is made.

(c) *Open enrollment periods.* For an election, or change in election, made during an open enrollment period, as described in § 422.62(a)(3) through (a)(6), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

(d) *Special election periods.* For an election or change of election made during a special election period as described in § 422.62(b), the effective date of coverage shall be determined by CMS, to the extent practicable, in a manner consistent with protecting the continuity of health benefits coverage.

(e) *Special election period for individual age 65.* For an election of coverage under original Medicare made during a special election period for an individual age 65 as described in § 422.62(c), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

[63 FR 35071, June 26, 1998, as amended at 65 FR 40317, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4718, Jan. 28, 2005]

§ 422.74 Disenrollment by the MA organization.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, an MA organization may not—

(1) Disenroll an individual from any MA plan it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment*—(1) *Optional disenrollment.* An MA organization may disenroll an individual from an MA plan it offers in any of the following circumstances:

(i) Any monthly basic and supplementary beneficiary premiums are not paid on a timely basis, subject to the grace period for late payment established under paragraph (d)(1) of this section.

(ii) The individual has engaged in disruptive behavior specified at paragraph (d)(2) of this section.

(iii) The individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in paragraph (d)(3) of this section.

(2) *Required disenrollment.* An MA organization must disenroll an individual from an MA plan it offers in any of the following circumstances:

(i) The individual no longer resides in the MA plan's service area as specified under paragraph (d)(4) of this section, is no longer eligible under § 422.50(a)(3)(ii), and optional continued enrollment has not been offered or elected under § 422.54.

(ii) The individual loses entitlement to Part A or Part B benefits as described in paragraph (d)(5) of this section.

(iii) Death of the individual as described in paragraph (d)(6) of this section.

(iv) Individuals enrolled in a specialized MA plan for special needs individuals that exclusively serves and enrolls special needs individuals who no longer meet the special needs status of that plan (or deemed continued eligibility, if applicable).

(3) *Plan termination or reduction of area where plan is available.* (i) *General rule.* An MA organization that has its contract for an MA plan terminated, that terminates an MA plan, or that discontinues offering the plan in any portion of the area where the plan had previously been available, must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at paragraph (d)(7) of this section, unless the exception in paragraph (b)(3)(ii) of this section applies.

(ii) *Exception.* When an MA organization discontinues offering an MA plan in a portion of its service area, the MA organization may elect to offer enrollees residing in all or portions of the affected area the option to continue enrollment in an MA plan offered by the organization, provided that there is no other MA plan offered in the affected area at the time of the organization's election. The organization may require an enrollee who chooses to continue enrollment to agree to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively through facilities designated by the organization within the plan service area.

(c) *Notice requirement.* If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(3) of this section (that is, other than death or loss of entitlement to Part A or Part B) the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) must—

(1) Be provided to the individual before submission of the disenrollment to CMS; and

(2) Include an explanation of the individual's right to a hearing under the MA organization's grievance procedures.

(d) *Process for disenrollment*—(1) *Monthly basic and supplementary premiums are not paid timely.* An MA organization may disenroll an individual from the MA plan for failure to pay basic and supplementary premiums under the following circumstances:

(i) The MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount, including:

(A) Alerting the individual that the premiums are delinquent;

(B) Providing the individual with a grace period, that is, an opportunity to pay past due premiums in full. The length of the grace period will be, at minimum, one month and will begin on the first day of the month for which the premium is unpaid.

(C) Advising the individual that failure to pay the premiums by the end of the grace period will result in termination of MA coverage.

(ii) The MA organization provides the enrollee with notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) If the enrollee fails to pay the premium for optional supplemental benefits but pays the basic premium and any mandatory supplemental premium, the MA organization has the option to discontinue the optional supplemental benefits and retain the individual as an MA enrollee.

(2) *Disruptive behavior.* (i) *Definition of disruptive behavior.* An MA plan enrollee is disruptive if his or her behavior substantially impairs the plan's ability to arrange for or provide services to the individual or other plan members. An individual cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* An organization may disenroll an individual whose behavior is disruptive as defined in 422.74(d)(2)(i) only after it meets the requirements described in this section and CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The MA organization must make a serious

effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities. In addition, the MA organization must inform the individual of the right to use the organization's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to the MA organization.

(iv) *Documentation*. The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (iii), and any extenuating circumstances. The MA organization may request from CMS the ability to decline future enrollment by the individual. The MA organization must submit this information and any documentation received by the beneficiary to CMS.

(v) *CMS review of the proposed disenrollment*. CMS will review the information submitted by the MA organization and any information submitted by the beneficiary (which the MA organization must forward to CMS) to determine if the MA organization has fulfilled the requirements to request disenrollment for disruptive behavior. If the organization has fulfilled the necessary requirements, CMS will review the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS will ensure that staff with appropriate clinical or medical expertise review the case before making the final decision. The MA organization will be required to provide a reasonable accommodation, as determined by CMS, for the individual in such exceptional circumstances that CMS deems necessary. CMS will notify the MA organization within 5 working days after making its decision.

(vi) *Effective date of disenrollment*. If CMS permits an MA organization to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the MA organization gives the individual notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section, unless otherwise determined by CMS.

(3) *Individual commits fraud or permits abuse of enrollment card*.—(i) *Basis for disenrollment*. An MA organization may disenroll the individual from an MA plan if the individual—

(A) Knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the MA plan; or

(B) Intentionally permits others to use his or her enrollment card to obtain services under the MA plan.

(ii) *Notice of disenrollment*. The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Report to CMS*. The MA organization must report to CMS any disenrollment based on fraud or abuse by the individual.

(4) *Individual no longer resides in the MA plan's service area*—(i) *Basis for disenrollment*. Unless continuation of enrollment is elected under § 422.54, the MA organization must disenroll an individual if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved—

(A) Out of the MA plan's service area; or

(B) From the residence in which the individual resided at the time of enrollment in the MA plan to an area outside the MA plan's service area, for those individuals who enrolled in the MA plan under the eligibility requirements at § 422.50(a)(3)(ii) or (a)(4).

(ii) *Special rule*. If the individual has not moved from the MA plan's service area (or residence, as described in paragraph (d)(4)(i)(B) of this section), but has left the service area (or residence) for more than 6 months, the MA organization must disenroll the individual from the plan, unless the exception in paragraph (d)(4)(iii) of this section applies.

(iii) *Exception*. If the MA plan covers services other than emergent, urgent, maintenance and poststabilization, and renal dialysis services (as described in § 422.100(b)(1)(iv) and § 422.113) when the

individual is out of the service area for a period of consecutive days longer than 6 months but less than 12 months, but within the United States (as defined in § 400.200 of this chapter), the MA organization may elect to offer to the individual the option of remaining enrolled in the MA plan if—

(A) The individual is disenrolled on the first day of the 13th month after the individual left the service area (or residence, if paragraph (d)(4)(i)(B) of this section applies);

(B) The individual understands and accepts any restrictions imposed by the MA plan on obtaining these services while absent from the MA plan's service area for the extended period; and

(C) The MA organization makes this option available to all Medicare enrollees who are absent for an extended period from the MA plan's service area. However, MA organizations may limit this option to enrollees who travel to certain areas, as defined by the MA organization, and who receive services from qualified providers who directly provide, arrange for, or pay for health care.

(iv) *Notice of disenrollment.* The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(5) *Loss of entitlement to Part A or Part B benefits.* If an individual is no longer entitled to Part A or Part B benefits, CMS notifies the MA organization that the disenrollment is effective the first day of the calendar month following the last month of entitlement to Part A or Part B benefits.

(6) *Death of the individual.* If the individual dies, disenrollment is effective the first day of the calendar month following the month of death.

(7) *Plan termination or area reduction.* (i) When an MA organization has its contract for an MA plan terminated, terminates an MA plan, or discontinues offering the plan in any portion of the area where the plan had previously been available, the MA organization must give each affected MA plan enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the MA program.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified in § 422.506(a)(2).

(e) *Consequences of disenrollment*—(1) *Disenrollment for non-payment of premiums, disruptive behavior, fraud or abuse, loss of Part A or Part B.* An individual who is disenrolled under paragraph (b)(1)(i), (b)(1)(ii), (b)(1)(iii), or paragraph (b)(2)(ii) of this section is deemed to have elected original Medicare.

(2) *Disenrollment based on plan termination, area reduction, or individual moves out of area.* (i) An individual who is disenrolled under paragraph (b)(2)(i) or (b)(3) of this section has a special election period in which to make a new election as provided in § 422.62(b)(1) and (b)(2).

(ii) An individual who fails to make an election during the special election period is deemed to have elected original Medicare.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40318, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4718, Jan. 28, 2005]

§ 422.80 Approval of marketing materials and election forms.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) of this section, an MA organization may not distribute any marketing materials (as defined in paragraph (b) of this section), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in paragraph (c); and

(ii) CMS does not disapprove the distribution of new material or form.

(2) The MA organization may distribute the marketing materials 5 days following their submission to CMS if—

(i) The MA organization is deemed by CMS to meet certain performance requirements established by CMS; or

(ii) The MA organization certifies that in the case of certain marketing materials designated by CMS, it followed all applicable marketing guidelines or used model language specified by CMS without modification.

(b) *Definition of marketing materials.* Marketing materials include any informational materials targeted to Medicare beneficiaries which:

(1) Promote the MA organization, or any MA plan offered by the MA organization;

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan offered by the MA organization;

(3) Explain the benefits of enrollment in an MA plan, or rules that apply to enrollees;

(4) Explain how Medicare services are covered under an MA plan, including conditions that apply to such coverage;

(5) Examples of marketing materials include, but are not limited to:

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (*e.g.*, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements (evidence of coverage), member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures *etc.*

(vii) Membership or claims processing activities (*e.g.*, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or annual notification information).

(c) *Guidelines for CMS review.* In reviewing marketing material or election forms under paragraph (a) of this section, CMS determines that the marketing materials:

(1) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(i) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(ii) Adequate written description of any supplemental benefits and services.

(iii) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(iv) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period (whether time-limited or continuous) in an appropriate manner, through appropriate media, throughout its service and continuation area.

(3) Include in the written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(4) Are not materially inaccurate or misleading or otherwise make material misreprepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(d) *Deemed approval (one-stop shopping).* If CMS has not disapproved the distribution of marketing materials or forms submitted by an MA organization with respect to an MA plan in an area, CMS is deemed not to have disapproved the distribution in all other areas covered by the MA plan and organization except with regard to any portion of the material or form that is specific to the particular area.

(e) *Standards for MA organization marketing.* (1) In conducting marketing activities, MA organizations may not:

(i) Provide for cash or other monetary rebates as an inducement for enrollment or otherwise. This does not

prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the MA plan, such as eligibility to enroll in a supplemental benefit plan that covers deductibles and coinsurance, or preventive services.

(ii) Engage in any discriminatory activity, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization. The MA organization may not claim it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the MA plan. It may, however, explain that the organization is approved for participation in Medicare.

(v) Distribute marketing materials for which, before expiration of the 45-day period (or 10 days as provided in paragraph (a)(1) of this section), the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.

(vi) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the materials have the concurrence of all MA organizations involved and have received prior approval by CMS. Physicians or providers may distribute health plan brochures (exclusive of application forms) at a health fair or in their offices. Physicians may discuss, in response to an individual patient's inquiry, the various benefits in different health plans.

(vii) Accept plan applications in provider offices or other places where health care is delivered.

(viii) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition shall not apply to MA plan names in effect on July 31, 2000.

(ix) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(2) In its marketing, the MA organization must:

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact, enrolled in the MA plan, and understand the rules applicable under the plan.

(f) *Employer group retiree marketing.* MA organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the MA organization, and furnish these materials only to the group members. While the materials must be submitted for approval under paragraph (a) of this section, CMS will not review portions of these materials that relate to employer group benefits.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40318, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 70 FR 4719, Jan. 28, 2005]

Subpart C—Benefits and Beneficiary Protections

SOURCE: 63 FR 35077, June 26, 1998, unless otherwise noted.

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an MA organization offering an MA plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c) of this section (and, to the extent applicable, the benefits described in § 422.102) by furnishing the benefits directly or through arrangements, or by paying for the benefits. CMS reviews these benefits subject to the requirements of § 422.100(g) and the requirements in subpart G of this part.

(b) *Services of noncontracting providers and suppliers.* (1) An MA organization must make timely and reasonable payment to or on behalf of the plan enrollee for the following services obtained from a provider or supplier that

does not contract with the MA organization to provide services covered by the MA plan:

(i) Ambulance services dispatched through 911 or its local equivalent as provided in § 422.113.

(ii) Emergency and urgently needed services as provided in § 422.113.

(iii) Maintenance and post-stabilization care services as provided in § 422.113.

(iv) Renal dialysis services provided while the enrollee was temporarily outside the plan's service area.

(v) Services for which coverage has been denied by the MA organization and found (upon appeal under subpart M of this part) to be services the enrollee was entitled to have furnished, or paid for, by the MA organization.

(2) An MA plan (and an MA MSA plan, after the annual deductible in § 422.103(d) has been met) offered by an MA organization satisfies paragraph (a) of this section with respect to benefits for services furnished by a noncontracting provider if that MA plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

(c) *Types of benefits.* An MA plan includes at a minimum basic benefits, and also may include mandatory and optional supplemental benefits.

(1) Basic benefits are all Medicare-covered services, except hospice services.

(2) Supplemental benefits, which consist of—

(i) Mandatory supplemental benefits are services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost-sharing.

(ii) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

(d) *Availability and structure of plans.* An MA organization offering an MA plan must offer it—

(1) To all Medicare beneficiaries residing in the service area of the MA plan;

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area, or segment of service area as provided in § 422.262(c)(2).

(e) *Multiple plans in one service area.* An MA organization may offer more than one MA plan in the same service area subject to the conditions and limitations set forth in this subpart for each MA plan.

(f) *CMS review and approval of MA benefits.* CMS reviews and approves MA benefits using written policy guidelines and requirements in this part and other CMS instructions to ensure that—

(1) Medicare-covered services meet CMS fee-for-service guidelines;

(2) MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services; and

(3) Benefit design meets other MA program requirements.

(g) *Benefits affecting screening mammography, influenza vaccine, and pneumoccal vaccine.* (1) Enrollees of MA organizations may directly access (through self-referral) screening mammography and influenza vaccine.

(2) MA organizations may not impose cost-sharing for influenza vaccine and pneumococcal vaccine on their MA plan enrollees.

(h) *Requirements relating to Medicare conditions of participation.* Basic benefits must be furnished through providers meeting the requirements in § 422.204(b)(3).

(i) *Provider networks.* The MA plans offered by an MA organization may share a provider network as long as each MA plan independently meets the access and availability standards described at § 422.112, as determined by CMS.

[65 FR 40319, June 29, 2000, as amended at 67 FR 13288, Mar. 22, 2002; 70 FR 4719, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§422.101 Requirements relating to basic benefits.

Except as specified in §422.318 (for entitlement that begins or ends during a hospital stay) and §422.320 (with respect to hospice care), each MA organization must meet the following requirements:

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with—

(1) CMS's national coverage determinations;

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by regulations in this part or related instructions; and

(3) Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan. If an MA plan covers geographic areas encompassing more than one local coverage policy area, the MA organization offering such an MA plan may elect to apply to plan enrollees in all areas uniformly the coverage policy that is the most beneficial to MA enrollees. MA organizations that elect this option must notify CMS before selecting the area that has local coverage policies that are most beneficial to enrollees as follows:

(i) An MA organization electing to adopt a uniform local coverage policy for a plan or plans must notify CMS at least 60 days before the date specified in §422.254(a)(1), which is 60 days before the date bid amounts are due for the subsequent year. Such notice must identify the plan or plans and service area or services areas to which the uniform local coverage policy or policies will apply, the competing local coverage policies involved, and a justification explaining why the selected local coverage policy or policies are most beneficial to MA enrollees.

(ii) CMS will review notices provided under paragraph (b)(3)(i) of this section, evaluate the selected local coverage policy or policies based on such factors as cost, access, geographic distribution of enrollees, and health status of enrollees, and notify the MA organization of its approval or denial of the selected uniform local coverage policy or policies.

(4) Instead of applying rules in paragraph (b)(3) of this section, and to the extent it exercises this option, an organization offering an MA regional plan in an MA region that covers more than one local coverage policy area must uniformly apply all of the local coverage policy determinations that apply in the selected local coverage policy area in that MA region to all parts of that same MA region. The selection of the single local coverage policy area's local coverage policy determinations to apply throughout the MA region is at the discretion of the MA regional plan and is not subject to CMS pre-approval.

(5) If an MA organization offering an MA local plan elects to exercise the option in paragraph (b)(3) of this section related to a local MA plan, or if an MA organization offering an MA regional plan elects to exercise the option in paragraph (b)(4) of this section related to an MA regional plan, then the MA organization must make information on the selected local coverage policy readily available, including through the Internet, to enrollees and health care providers.

(c) MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of posthospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

(d) *Special cost-sharing rules for MA regional plans.* In addition to the requirements in paragraph (a) through paragraph (c) of this section, MA regional plans must provide for the following:

(1) *Single deductible.* MA regional plans, to the extent they apply a deductible, are permitted to have only a single deductible related to combined

Medicare Part A and Part B services (to the extent they have a deductible). Applicability of the single deductible may be differential for specific in-network services and may also be waived for preventative services or other items and services.

(2) *Catastrophic limit.* MA regional plans are required to provide for a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the original Medicare fee-for-service program (Part A and Part B benefits).

(3) *Total catastrophic limit.* MA regional plans are required to provide a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the original Medicare fee-for-service program. This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under original Medicare, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section.

(4) *Tracking of deductible and catastrophic limits and notification.* MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) of this section based on incurred out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the deductible (if any) or a limit has been reached.

(e) *Other rules for MA regional plans.* (1) MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within or outside of the network of contracted providers.

(2) In applying the actuarially equivalent level of cost-sharing with respect to MA bids related to benefits under the original Medicare program option as set forth at § 422.256(b)(3), only the catastrophic limit on out-of-pocket expenses for in-network benefits in paragraph (d)(2) of this section will be taken into account.

[65 FR 40319, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003; 70 FR 4720, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.102 Supplemental benefits.

(a) *Mandatory supplemental benefits.* (1) Subject to CMS approval, an MA organization may require Medicare enrollees of an MA plan (other than an MSA plan) to accept or pay for services in addition to Medicare-covered services described in § 422.101.

(2) If the MA organization imposes mandatory supplemental benefits, it must impose them on all Medicare beneficiaries enrolled in the MA plan.

(3) CMS approves mandatory supplemental benefits if the benefits are designed in accordance with CMS' guidelines and requirements as stated in this part and other written instructions.

(4) Beginning in 2006, an MA plan may reduce cost sharing below the actuarial value specified in section 1854(e)(4)(A) of the Act only as a mandatory supplemental benefit.

(b) *Optional supplemental benefits.* Except as provided in § 422.104 in the case of MSA plans, each MA organization may offer (for election by the enrollee and without regard to health status) services that are not included in the basic benefits as described in § 422.100(c) and any mandatory supplemental benefits described in paragraph (a) of this section. Optional supplemental benefits are purchased at the discretion of the enrollee and must be offered to all Medicare beneficiaries enrolled in the MA plan.

(c) *Payment for supplemental services.* All supplemental benefits are paid for in full, directly by (or on behalf of) the enrollee of the MA plan.

(d) *Marketing of supplemental benefits.* MA organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of groups and individual services.

[65 FR 40320, June 29, 2000, as amended at 70 FR 4720, Jan. 28, 2005]

§ 422.103 Benefits under an MA MSA plan.

(a) *General rule.* An MA organization offering an MA MSA plan must make available to an enrollee, or provide reimbursement for, at least the services described in § 422.101 after the enrollee incurs countable expenses equal to the

amount of the plan's annual deductible.

(b) *Countable expenses.* An MA organization offering an MA MSA plan must count toward the annual deductible at least all amounts that would be paid for the particular service under original Medicare, including amounts that would be paid by the enrollee as deductibles or coinsurance.

(c) *Services after the deductible.* For services received by the enrollee after the annual deductible is satisfied, an MA organization offering an MA MSA plan must pay, at a minimum, the lesser of the following amounts:

(1) 100 percent of the expense of the services.

(2) 100 percent of the amounts that would have been paid for the services under original Medicare, including amounts that would be paid by the enrollee as deductibles and coinsurance.

(d) *Annual deductible.* The annual deductible for an MA MSA plan—

(1) For contract year 1999, may not exceed $6,000; and

(2) For subsequent contract years may not exceed the deductible for the preceding contract year, increased by the national per capita growth percentage determined under § 422.306(a)(2).

[63 FR 35077, June 26, 1998, as amended at 70 FR 4720, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.104 Special rules on supplemental benefits for MA MSA plans.

(a) An MA organization offering an MA MSA plan may not provide supplemental benefits that cover expenses that count towards the deductible specified in § 422.103(d).

(b) In applying the limitation of paragraph (a) of this section, the following kinds of policies are not considered as covering the deductible:

(1) A policy that provides coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

(2) A policy of insurance in which substantially all of the coverage relates to liabilities incurred under workers' compensation laws, tort liabilities, liabilities relating to use or ownership of property, and any other similar liabilities that CMS may specify by regulation.

(3) A policy of insurance that provides coverage for a specified disease or illness or pays a fixed amount per day (or other period) of hospitalization.

§ 422.105 Special rules for self-referral and point of service option.

(a) *Self-referral.* When an MA plan member receives an item or service of the plan that is covered upon referral or pre-authorization from a contracted provider of that plan, the member cannot be financially liable for more than the normal in-plan cost sharing, if the member correctly identified himself or herself as a member of that plan to the contracted provider before receiving the covered item or service, unless the contracted provider can show that the enrollee was notified prior to receiving the item or service that the item or service is covered only if further action is taken by the enrollee.

(b) *Point of service option.* As a general rule, a POS benefit is an option that an MA organization may offer in an MA coordinated care plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer A POS option—

(1) Before January 1, 2006, under a coordinated care plan as an additional benefit as described in section 1854(f)(1)(A) of the Act;

(2) Under a coordinated care plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under a coordinated care plan as an optional supplemental benefit as described in § 422.102(b).

(4) An MA regional plan or local MA PPO is permitted to offer a POS–LIKE benefit as described in paragraphs (b)(2) or (b)(3) of this section as a supplemental benefit. An MA regional plan or local MA PPO may offer a POS–LIKE option as a supplemental benefit where cost sharing for out-of-network services is reduced, in a limited manner, for services obtained from out-of-network providers. Offering a POS–LIKE supplemental benefit does not affect the MA regional plan's or local MA PPO's responsibility to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within the network of contracted providers.

(c) *Ensuring availability and continuity of care.* An MA network plan that includes a POS benefit must continue to provide all benefits and ensure access as required under this subpart.

(d) *Enrollee information and disclosure.* The disclosure requirements specified in § 422.111 apply in addition to the following requirements:

(1) *Written rules.* MA organizations must maintain written rules on how to obtain health benefits through the POS benefit.

(2) *Evidence of coverage document.* The MA organization must provide to beneficiaries enrolling in a plan with a POS benefit an ''evidence of coverage'' document, or otherwise provide written documentation, that specifies all costs and possible financial risks to the enrollee, including—

(i) Any premiums and cost-sharing for which the enrollee is responsible;

(ii) Annual limits on benefits and on out-of-pocket expenditures;

(iii) Potential financial responsibility for services for which the plan denies payment because they were not covered under the POS benefit, or exceeded the dollar limit for the benefit; and

(iv) The annual maximum out-of-pocket expense an enrollee could incur.

(e) *Prompt payment.* Health benefits payable under the POS benefit are subject to the prompt payment requirements in § 422.520.

(f) *POS-related data.* An MA organization that offers a POS benefit through an MA plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by CMS.

[63 FR 35077, June 26, 1998, as amended at 65 FR 40320, June 29, 2000; 70 FR 4721, Jan. 28, 2005]

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

(a) *General rule.* If an MA organization contracts with an employer, labor organization, or the trustees of a fund established by one or more employers or labor organizations that cover enrollees in an MA plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an MA plan, the enrollees must be provided the same benefits as all other enrollees in the MA plan, with the employer, labor organization, fund trustees, or Medicaid benefits supplementing the MA plan benefits. Jurisdiction regulating benefits under these circumstances is as follows:

(1) All requirements of this part that apply to the MA program apply to the MA plan coverage and benefits provided to enrollees eligible for benefits under an employer, labor organization, trustees of a fund established by one or more employers or labor organizations, or Medicaid contract.

(2) Employer benefits that complement an MA plan, which are not part of the MA plan, are not subject to review or approval by CMS.

(3) Medicaid benefits are not reviewed under this part, but are subject to appropriate CMS review under the Medicaid program. MA plan benefits provided to individuals entitled to Medicaid benefits provided by the MA organization under a contract with the State Medicaid agency are subject to MA rules and requirements.

(b) *Examples.* Permissible employer, labor organization, benefit fund trustee, or Medicaid plan benefits include the following:

(1) Payment of a portion or all of the MA basic and supplemental premiums.

(2) Payment of a portion or all of other cost-sharing amounts approved for the MA plan.

(3) Other employer-sponsored benefits that may require additional premium and cost-sharing, or other benefits provided by the organization under a contract with the State Medicaid agency.

(c) *Waiver or modification of contracts with MA organizations.* (1) MA organizations may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, MA plans under contracts between MA organizations and employers, labor organizations, or the trustees

of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of the labor organizations.

(2) Approved waivers or modifications under this paragraph granted to any MA organization may be used by any other similarly situated MA organization in developing its bid.

(d) *Employer sponsored MA plans for plan years beginning on or after January 1, 2006.* (1) CMS may waive or modify any requirement in this part or Part D that hinders the design of, the offering of, or the enrollment in, an MA plan (including an MA-PD plan) offered by one or more employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof), or that is offered, sponsored or administered by an entity on behalf of one or more employers or labor organizations, to furnish benefits to the employers' employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations. Any entity seeking to offer, sponsor, or administer such an MA plan described in this paragraph may request, in writing, from CMS, a waiver or modification of requirements in this part that hinder the design of, the offering of, or the enrollment in, such MA plan.

(2) An MA plan described in this paragraph may restrict the enrollment of individuals in that plan to individuals who are beneficiaries and participants in that plan.

(3) Approved waivers or modifications under this paragraph granted to any MA plan may be used by any other similarly situated MA plan in developing its bid.

[65 FR 40320, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003; 70 FR 4721, Jan. 28, 2005]

§422.108 Medicare secondary payer (MSP) procedures.

(a) *Basic rule.* CMS does not pay for services to the extent that Medicare is not the primary payer under section 1862(b) of the Act and part 411 of this chapter.

(b) *Responsibilities of the MA organization.* The MA organization must, for each MA plan—

(1) Identify payers that are primary to Medicare under section 1862(b) of the Act and part 411 of this chapter;

(2) Identify the amounts payable by those payers; and

(3) Coordinate its benefits to Medicare enrollees with the benefits of the primary payers.

(c) *Collecting from other entities.* The MA organization may bill, or authorize a provider to bill, other individuals or entities for covered Medicare services for which Medicare is not the primary payer, as specified in paragraphs (d) and (e) of this section.

(d) *Collecting from other insurers or the enrollee.* If a Medicare enrollee receives from an MA organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the MA organization may bill, or authorize a provider to bill any of the following—

(1) The insurance carrier, the employer, or any other entity that is liable for payment for the services under section 1862(b) of the Act and part 411 of this chapter.

(2) The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses.

(e) *Collecting from group health plans (GHPs) and large group health plans (LGHPs).* An MA organization may bill a GHP or LGHP for services it furnishes to a Medicare enrollee who is also covered under the GHP or LGHP and may bill the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP.

(f) *MSP rules and State laws.* Consistent with §422.402 concerning the Federal preemption of State law, the rules established under this section supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to MA plans. A State cannot take away an MA organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is

not the primary payer. The MA organization will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations in subparts B through D of part 411 of this chapter.

[63 FR 35077, June 26, 1998, as amended at 65 FR 40320, June 29, 2000; 70 FR 4721, Jan. 28, 2005]

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits.

(a) *Definitions*. The term *significant cost*, as it relates to a particular NCD or legislative change in benefits, means either of the following:

(1) The average cost of furnishing a single service exceeds a cost threshold that—

(i) For calendar years 1998 and 1999, is $100,000; and

(ii) For calendar year 2000 and subsequent calendar years, is the preceding year's dollar threshold adjusted to reflect the national per capita growth percentage described in § 422.308(a).

(2) The estimated cost of Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national average per capita costs.

(b) *General rule*. If CMS determines and announces that an individual NCD or legislative change in benefits meets the criteria for significant cost described in paragraph (a) of this section, a MA organization is not required to assume risk for the costs of that service or benefit until the contract year for which payments are appropriately adjusted to take into account the cost of the NCD service or legislative change in benefits. If CMS determines that an NCD or legislative change in benefits does not meet the ''significant cost'' threshold described in § 422.109(a), the MA organization is required to provide coverage for the NCD or legislative change in benefits and assume risk for the costs of that service or benefit as of the effective date stated in the NCD or specified in the legislation.

(c) *Before payment adjustments become effective*. Before the contract year that payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits become effective, the service or benefit is not included in the MA organization's contract with CMS, and is not a covered benefit under the contract. The following rules apply to these services or benefits:

(1) Medicare payment for the service or benefit is made directly by the fiscal intermediary and carrier to the provider furnishing the service or benefit in accordance with original Medicare payment rules, methods, and requirements.

(2) Costs for NCD services or legislative changes in benefits for which CMS intermediaries and carriers will not make payment and are the responsibility of the MA organization are—

(i) Services necessary to diagnose a condition covered by the NCD or legislative changes in benefits;

(ii) Most services furnished as follow-up care to the NCD service or legislative change in benefits;

(iii) Any service that is already a Medicare-covered service and included in the annual MA capitation rate or previously adjusted payments; and

(iv) Any services, including the costs of the NCD service or legislative change in benefits, to the extent the MA organization is already obligated to cover it as a supplemental benefit under § 422.102.

(3) Costs for significant cost NCD services or legislative changes in benefits for which CMS fiscal intermediaries and carriers will make payment are those Medicare costs not listed in paragraphs (c)(2)(i) through (c)(2)(iv) of this section.

(4) Beneficiaries are liable for any applicable coinsurance amounts.

(d) *After payment adjustments become effective*. For the contract year in which payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits are in effect, the service or benefit is included in the MA organization's contract with CMS, and is a covered benefit under the contract. Subject to all applicable rules under this part, the MA organization must furnish, arrange, or pay for the NCD service or legislative change in benefits. MA organizations may establish separate plan rules for these services and

benefits, subject to CMS review and approval. CMS may, at its discretion, issue overriding instructions limiting or revising the MA plan rules, depending on the specific NCD or legislative change in benefits. For these services or benefits, the Medicare enrollee will be responsible for MA plan cost sharing, as approved by CMS or unless otherwise instructed by CMS.

[68 FR 50856, Aug. 22, 2003, as amended at 70 FR 4721, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.110 Discrimination against beneficiaries prohibited.

(a) *General prohibition.* Except as provided in paragraph (b) of this section, an MA organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan offered by the organization on the basis of any factor that is related to health status, including, but not limited to the following:

(1) Medical condition, including mental as well as physical illness.

(2) Claims experience.

(3) Receipt of health care.

(4) Medical history.

(5) Genetic information.

(6) Evidence of insurability, including conditions arising out of acts of domestic violence.

(7) Disability.

(b) *Exception.* An MA organization may not enroll an individual who has been medically determined to have end-stage renal disease. However, an enrollee who develops end-stage renal disease while enrolled in a particular MA organization may not be disenrolled for that reason. An individual who is an enrollee of a particular MA organization, and who resides in the MA plan service area at the time he or she first becomes MA eligible, or, an individual enrolled by an MA organization that allows those who reside outside its MA service area to enroll in an MA plan as set forth at § 422.50(a)(3)(ii), then that individual is considered to be ''enrolled'' in the MA organization for purposes of the preceding sentence.

[63 FR 35077, June 26, 1998; 63 FR 52612, Oct. 1, 1998; 64 FR 7980, Feb. 17, 1999, as amended at 65 FR 40321, June 29, 2000; 70 FR 4721, Jan. 28, 2005]

§ 422.111 Disclosure requirements.

(a) *Detailed description.* An MA organization must disclose the information specified in paragraph (b) of this section—

(1) To each enrollee electing an MA plan it offers;

(2) In clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of plan description.* The description must include the following information:

(1) *Service area.* The MA plan's service area and any enrollment continuation area.

(2) *Benefits.* The benefits offered under a plan, including applicable conditions and limitations, premiums and cost-sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits; and to the extent it offers Part D as an MA-PD plan, the information in § 423.128 of this chapter; and for purposes of comparison-

(i) The benefits offered under original Medicare, including the content specified in paragraph (f)(1) of this section;

(ii) For an MA MSA plan, the benefits under other types of MA plans; and

(iii) The availability of the Medicare hospice option and any approved hospices in the service area, including those the MA organization owns, controls, or has a financial interest in.

(3) *Access.* (i) The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets the requirements of § 422.112 and § 422.114 for access to services offered under the plan.

(ii) The process MA regional plan enrollees should follow to secure in-network cost sharing when covered services are not readily available from contracted network providers.

(4) Out-of-area coverage provided under the plan, including coverage provided to individuals eligible to enroll in the plan under § 422.50(a)(3)(ii).

(5) *Emergency coverage.* Coverage of emergency services, including—

(i) Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at § 422.113;

(ii) The appropriate use of emergency services, stating that prior authorization cannot be required;

(iii) The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent; and

(iv) The locations where emergency care can be obtained and other locations at which contracting physicians and hospitals provide emergency services and post-stabilization care included in the MA plan.

(6) *Supplemental benefits.* Any mandatory or optional supplemental benefits and the premium for those benefits.

(7) *Prior authorization and review rules.* Prior authorization rules and other review requirements that must be met in order to ensure payment for the services. The MA organization must instruct enrollees that, in cases where noncontracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the MA organization for processing and determination of enrollee liability, if any.

(8) *Grievance and appeals procedures.* All grievance and appeals rights and procedures.

(9) *Quality improvement program.* A description of the quality improvement program required under § 422.152.

(10) *Disenrollment rights and responsibilities.*

(11) *Catastrophic caps and single deductible.* MA organizations sponsoring MA regional plans are required to provide enrollees a description of the catastrophic stop-loss coverage and single deductible (if any) applicable under the plan.

(c) *Disclosure upon request.* Upon request of an individual eligible to elect an MA plan, an MA organization must provide to the individual the following information:

(1) The information required in paragraph (f) of this section.

(2) The procedures the organization uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by the Secretary. Such disputes shall be categorized as

(i) Grievances according to § 422.564; and

(ii) Appeals according to § 422.578 et. seq.

(4) A summary description of the method of compensation for physicians.

(5) Financial condition of the MA organization, including the most recently audited information regarding, at least, a description of the financial condition of the MA organization offering the plan.

(d) *Changes in rules.* If an MA organization intends to change its rules for an MA plan, it must:

(1) Submit the changes for CMS review under the procedures of § 422.80.

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

(3) For all other changes, notify all enrollees at least 30 days before the intended effective date of the changes.

(e) *Changes to provider network.* The MA organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

(f) *Disclosable information*—(1) *Benefits under original Medicare.* (i) Covered services.

(ii) Beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts.

(iii) Any beneficiary liability for balance billing.

(2) *Enrollment procedures.* Information and instructions on how to exercise election options under this subpart.

(3) *Rights.* A general description of procedural rights (including grievance and appeals procedures) under original Medicare and the MA program and the right to be protected against discrimination based on factors related to health status in accordance with § 422.110.

(4) *Potential for contract termination.* The fact that an MA organization may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in that organization's MA plan.

(5) *Benefits.* (i) Covered services beyond those provided under original Medicare.

(ii) Any beneficiary cost-sharing.

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an MA MSA plan, the amount of the annual MSA deposit.

(v) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vi) The types of providers that participate in the plan's network and the extent to which an enrollee may select among those providers.

(vii) The coverage of emergency and urgently needed services.

(6) *Premiums.* (i) The MA monthly basic beneficiary premiums.

(ii) The MA monthly supplemental beneficiary premium.

(iii) The reduction in Part B premiums, if any.

(7) *The plan's service area.*

(8) *Quality and performance indicators* for benefits under a plan to the extent they are available as follows (and how they compare with indicators under original Medicare):

(i) Disenrollment rates for Medicare enrollees for the 2 previous years, excluding disenrollment due to death or moving outside the plan's service area, calculated according to CMS guidelines.

(ii) Medicare enrollee satisfaction.

(iii) Health outcomes.

(iv) Plan-level appeal data.

(v) The recent record of plan compliance with the requirements of this part, as determined by the Secretary.

(vi) Other performance indicators.

(9) *Supplemental benefits.* Whether the plan offers mandatory and optional supplemental benefits, including any reductions in cost sharing offered as a mandatory supplemental benefit as permitted under section 1852(a)(3) of the Act (and implementing regulations at § 422.102) and the terms, conditions, and premiums for those benefits.

(10) The names, addresses, and phone numbers of contracted providers from whom the enrollee may obtain in-network coverage in other parts of the service area.

(11) If an MA organization exercises the option in § 422.101(b)(3) or (b)(4) related to an MA plan, then it must make the local coverage determination that applies to members of that plan readily available to providers, including through a web site on the Internet.

(12) To the extent an MA organization has a web site or provides MA plan information through the Internet, then it must also post copies of its Evidence of Coverage, Summary of Benefits and information (names, addresses, phone numbers, specialty) on the network of contracted providers on an Internet web site. Such posting does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees.

[63 FR 35077, June 26, 1998, as amended at 64 FR 7980, Feb. 17, 1999; 65 FR 40321, June 29, 2000; 68 FR 50857, Aug. 22, 2003; 70 FR 4722, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.112 Access to services.

(a) *Rules for coordinated care plans.* An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the MA organization must meet the following requirements:

(1) *Provider network*. (i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(ii) *Exception*: MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.

(2) *PCP panel*. Establish a panel of PCPs from which the enrollee may select a PCP. If an MA organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, the MA organization must either assign a PCP for purposes of making the needed referral or make other arrangements to ensure access to medically necessary specialty care.

(3) *Specialty care*. Provide or arrange for necessary specialty care, and in particular give women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services provided as basic benefits (as defined in § 422.2). The MA organization arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

(4) *Service area expansion*. If seeking a service area expansion for an MA plan, demonstrate that the number and type of providers available to plan enrollees are sufficient to meet projected needs of the population to be served.

(5) *Credentialed providers*. Demonstrate to CMS that its providers in an MA plan are credentialed through the process set forth at § 422.204(a).

(6) *Written standards*. Establish written standards for the following:

(i) Timeliness of access to care and member services that meet or exceed standards established by CMS. Timely access to care and member services within a plan's provider network must be continuously monitored to ensure compliance with these standards, and the MA organization must take corrective action as necessary.

(ii) Policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations.

(iii) Provider consideration of beneficiary input into the provider's proposed treatment plan.

(7) *Hours of operation*. Ensure that—

(i) The hours of operation of its MA plan providers are convenient to the population served under the plan and do not discriminate against Medicare enrollees; and

(ii) Plan services are available 24 hours a day, 7 days a week, when medically necessary.

(8) *Cultural considerations*. Ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

(9) *Ambulance services, emergency and urgently needed services, and post-stabilization care services coverage*. Provide coverage for ambulance services, emergency and urgently needed services, and post-stabilization care services in accordance with § 422.113.

(b) *Continuity of care*. MA organizations offering coordinated care plans must ensure continuity of care and integration of services through arrangements with contracted providers that include—

(1) Policies that specify under what circumstances services are coordinated and the methods for coordination;

(2) Offering to provide each enrollee with an ongoing source of primary care and providing a primary care source to each enrollee who accepts the offer;

(3) Programs for coordination of plan services with community and social services generally available through contracting or noncontracting providers in the area served by the MA plan, including nursing home and community-based services; and

(4) Procedures to ensure that the MA organization and its provider network have the information required for effective and continuous patient care and

quality review, including procedures to ensure that—

(i) The MA organization makes a ''best-effort'' attempt to conduct an initial assessment of each enrollee's health care needs, including following up on unsuccessful attempts to contact an enrollee, within 90 days of the effective date of enrollment;

(ii) Each provider, supplier, and practitioner furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the MA organization, taking into account professional standards; and

(iii) There is appropriate and confidential exchange of information among provider network components.

(5) Procedures to ensure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health; and

(6) Systems to address barriers to enrollee compliance with prescribed treatments or regimens.

(c) *Essential hospital.* An MA regional plan may seek, upon application to CMS, to designate a noncontracting hospital as an essential hospital as defined in section 1858(h) of the Act under the following conditions:

(1) The hospital that the MA regional plan seeks to designate as essential is a general acute care hospital identified as a ''subsection(d)'' hospital as defined in section 1886(d)(1)(B) of the Act.

(2) The MA regional plan provides convincing evidence to CMS that the MA regional plan needs to contract with the hospital as a condition of meeting access requirements under this section.

(3) The MA regional plan must establish that it made a ''good faith'' effort to contract with the hospital to be designated as an essential hospital and that the hospital refused to contract with it despite its ''good faith'' effort. A ''good faith'' effort to contract will be established to the extent that the MA regional plan can show it has offered the hospital a contract providing for the payment of rates in an amount no less than the amount the hospital would have received had payment been made under section 1886(d) of the Act.

(4) The MA regional plan must establish that there are no competing Medicare participating hospitals in the area to which MA regional plan enrollees could reasonably be referred for inpatient hospital services.

(5) The hospital that is to be designated as an essential hospital provides convincing evidence to CMS that the amounts normally payable under section 1886 of the Act (and which the MA regional plan has agreed to pay) will be less than the hospital's actual costs of providing care to the MA regional plan's enrollee.

(6) If CMS determines the requirements in paragraphs (c)(1) through (c)(5) of this section have been met, it will make payment to the essential hospital in accordance with section 1858(h)(2) of the Act based on the order in which claims are received, as limited by the amounts specified in section 1858(h)(3) of the Act.

(7) If CMS determines the requirements in paragraphs (c)(1) through (c)(4) of this section have been met, (and if they continue to be met upon annual renewal of the CMS contract with the MA organization offering the MA regional plan), then the hospital designated by the MA regional plan in paragraph (c)(1) of this section shall be ''deemed'' to be a network hospital to that MA regional plan based on the exception in paragraph (a)(1)(ii) of this section and normal in-network inpatient hospital cost sharing levels (including the catastrophic limit described in §422.101(d)(2)) shall apply to all plan members accessing covered inpatient hospital services in that hospital.

[64 FR 7980, Feb. 17, 1999, as amended at 65 FR 40321, June 29, 2000; 70 FR 4722, Jan. 28, 2005]

§422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

(a) *Ambulance services.* The MA organization is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, where other means of transportation would endanger the beneficiary's health.

(b) *Emergency and urgently needed services*—(1) *Definitions*.

(i) *Emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(A) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(ii) *Emergency services* means covered inpatient and outpatient services that are—

(A) Furnished by a provider qualified to furnish emergency services; and

(B) Needed to evaluate or stabilize an emergency medical condition.

(iii) *Urgently needed services* means covered services that are not emergency services as defined this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or, under unusual and extraordinary circumstances, provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

(A) As a result of an unforeseen illness, injury, or condition; and

(B) It was not reasonable given the circumstances to obtain the services through the organization offering the MA plan.

(2) *MA organization financial responsibility*. The MA organization is financially responsible for emergency and urgently needed services—

(i) Regardless of whether the services are obtained within or outside the MA organization;

(ii) Regardless of whether there is prior authorization for the services.

(A) Instructions to seek prior authorization for emergency or urgently needed services may not be included in any materials furnished to enrollees (including wallet card instructions), and enrollees must be informed of their right to call 911.

(B) Instruction to seek prior authorization before the enrollee has been stabilized may not be included in any materials furnished to providers (including contracts with providers);

(iii) In accordance with the prudent layperson definition of *emergency medical condition* regardless of final diagnosis;

(iv) For which a plan provider or other MA organization representative instructs an enrollee to seek emergency services within or outside the plan; and

(v) With a limit on charges to enrollees for emergency department services of $50 or what it would charge the enrollee if he or she obtained the services through the MA organization, whichever is less.

(3) *Stabilized condition*. The physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the MA organization.

(c) *Maintenance care and post-stabilization care services* (hereafter together referred to as ''post-stabilization care services'').

(1) *Definition*. *Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (c)(2)(iii) of this section, to improve or resolve the enrollee's condition.

(2) *MA organization financial responsibility*. The MA organization—

(i) Is financially responsible (consistent with § 422.214) for post-stabilization care services obtained within or outside the MA organization that are pre-approved by a plan provider or other MA organization representative;

(ii) Is financially responsible for post-stabilization care services obtained within or outside the MA organization that are not pre-approved by a plan provider or other MA organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the

MA organization for pre-approval of further post-stabilization care services;

(iii) Is financially responsible for post-stabilization care services obtained within or outside the MA organization that are not pre-approved by a plan provider or other MA organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

(A) The MA organization does not respond to a request for pre-approval within 1 hour;

(B) The MA organization cannot be contacted; or

(C) The MA organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the MA organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue with care of the patient until a plan physician is reached or one of the criteria in §422.113(c)(3) is met; and

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the MA organization. For purposes of cost sharing, post-stabilization care services begin upon inpatient admission.

(3) *End of MA organization's financial responsibility*. The MA organization's financial responsibility for post-stabilization care services it has not pre-approved ends when—

(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

(ii) A plan physician assumes responsibility for the enrollee's care through transfer;

(iii) An MA organization representative and the treating physician reach an agreement concerning the enrollee's care; or

(iv) The enrollee is discharged.

[65 FR 40322, June 29, 2000, as amended at 70 FR 4723, Jan. 28, 2005]

§422.114 Access to services under an MA private fee-for-service plan.

(a) *Sufficient access*. (1) An MA organization that offers an MA private fee-for-service plan must demonstrate to CMS that it has sufficient number and range of providers willing to furnish services under the plan.

(2) CMS finds that an MA organization meets the requirement in paragraph (a)(1) of this section if, with respect to a particular category of health care providers, the MA organization has—

(i) Payment rates that are not less than the rates that apply under original Medicare for the provider in question;

(ii) Contracts or agreements with a sufficient number and range of providers to furnish the services covered under the MA private fee-for-service plan; or

(iii) A combination of paragraphs (a)(2)(i) and (a)(2)(ii) of this section.

(b) *Freedom of choice*. MA fee-for-service plans must permit enrollees to obtain services from any entity that is authorized to provide services under Medicare Part A and Part B and agrees to provide services under the terms of the plan.

(c) *Contracted network*. Private fee-for-service plans that meet network adequacy requirements for a category of health care professional or provider by meeting the requirements in paragraph (a)(2)(ii) of this section may provide for a higher beneficiary copayment in the case of health care professionals or providers of that same category who do not have contracts or agreements to provide covered services under the terms of the plan.

[63 FR 35077, June 26, 1998, as amended at 70 FR 4723, Jan. 28, 2005]

§422.118 Confidentiality and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, an MA organization must establish procedures to do the following:

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The MA organization must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information will be used within the organization; and

(2) To whom and for what purposes it will disclose the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

[65 FR 40323, June 29, 2000]

§ 422.128 Information on advance directives.

(a) Each MA organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in subpart I of part 489 of this chapter. For purposes of this part, *advance directive* has the meaning given the term in § 489.100 of this chapter.

(b) An MA organization must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the MA organization.

(1) An MA organization must provide written information to those individuals with respect to the following:

(i) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning their medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Providers may contract with other entities to furnish this information but remain legally responsible for ensuring that the requirements of this section are met. The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law.

(ii) The MA organization's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the MA organization cannot implement an advance directive as a matter of conscience. At a minimum, this statement must do the following:

(A) Clarify any differences between institution-wide conscientious objections and those that may be raised by individual physicians.

(B) Identify the state legal authority permitting such objection.

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(D) Provide the information specified in paragraph (a)(1) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the MA organization may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The MA organization is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(E) Document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive.

(F) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive.

(G) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives.

(H) Provide for education of staff concerning its policies and procedures on advance directives.

(I) Provide for community education regarding advance directives that may include material required in paragraph (a)(1)(i) of this section, either directly or in concert with other providers or

entities. Separate community education materials may be developed and used, at the discretion of the MA organization. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An MA organization must be able to document its community education efforts.

(2) The MA organization—

(i) Is not required to provide care that conflicts with an advance directive; and

(ii) Is not required to implement an advance directive if, as a matter of conscience, the MA organization cannot implement an advance directive and State law allows any health care provider or any agent of the provider to conscientiously object.

(3) The MA organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State survey and certification agency.

§ 422.132 Protection against liability and loss of benefits.

Enrollees of MA organizations are entitled to the protections specified in § 422.504(g).

[63 FR 35077, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005

§ 422.133 Return to home skilled nursing facility.

(a) *General rule*. MA plans must provide coverage of posthospital extended care services to Medicare enrollees through a home skilled nursing facility if the enrollee elects to receive the coverage through the home skilled nursing facility, and if the home skilled nursing facility either has a contract with the MA organization or agrees to accept substantially similar payment under the same terms and conditions that apply to similar skilled nursing facilities that contract with the MA organization.

(b) *Definitions*. In this subpart, *home skilled nursing facility* means—

(1) The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of posthospital extended care services;

(2) A skilled nursing facility that is providing posthospital extended care services through a continuing care retirement community in which the MA plan enrollee was a resident at the time of admission to the hospital. A continuing care retirement community is an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period; or

(3) The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from the hospital.

(4) If an MA organization elects to furnish SNF care in the absence of a prior qualifying hospital stay under § 422.101(c), then that SNF care is also subject to the home skilled nursing facility rules in this section. In applying the provisions of this section to coverage under this paragraph, references to a hospitalization, or discharge from a hospital, are deemed to refer to wherever the enrollee resides immediately before admission for extended care services.

(c) *Coverage no less favorable*. The posthospital extended care scope of services, cost-sharing, and access to coverage provided by the home skilled nursing facility must be no less favorable to the enrollee than posthospital extended care services coverage that would be provided to the enrollee by a skilled nursing facility that would be otherwise covered under the MA plan.

(d) *Exceptions*. The requirement to allow an MA plan enrollee to elect to return to the home skilled nursing facility for posthospital extended care services after discharge from the hospital does not do the following:

(1) Require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under Part A for Medicare beneficiaries not enrolled in the MA plan.

(2) Prevent a skilled nursing facility from refusing to accept, or imposing

conditions on the acceptance of, an enrollee for the receipt of posthospital extended care services.

[68 FR 50857, Aug. 22, 2003, as amended at 70 FR 4723, Jan. 28, 2005]

Subpart D—Quality Improvement

SOURCE: 63 FR 35082, June 26, 1998, unless otherwise noted.

§ 422.152 Quality improvement program.

(a) *General rule.* Each MA organization (other than MA private-fee-for-service and MSA plans) that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets the applicable requirements of this section for the services it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must—

(1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program;

(2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, and meet the requirements of paragraph (d) of this section; and

(3) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

(b) *Requirements for MA coordinated care plans (except for regional MA plans) and including local PPO plans that are offered by organizations that are licensed or organized under State law as HMOs.* An MA coordinated care plan's (except for regional PPO plans and local PPO plans as defined in paragraph (e) of this section) quality improvement program must—

(1) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(2) Have in effect mechanisms to detect both underutilization and overutilization of services.

(3) Measure and report performance. The organization offering the plan must do the following:

(i) Measure performance under the plan, using the measurement tools required by CMS, and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64.

(4) Special rule for MA local PPO-type plans that are offered by an organization that is licensed or organized under State law as a health maintenance organization must meet the requirements specified in paragraphs (b)(1) through (b)(3) of this section.

(c) *Chronic care improvement program requirements.* Develop criteria for a chronic care improvement program. These criteria must include—

(1) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program; and

(2) Mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program.

(d) *Quality improvement projects.* (1) Quality improvement projects are an organization's initiatives that focus on specified clinical and nonclinical areas and that involve the following:

(i) Measurement of performance.

(ii) System interventions, including the establishment or alteration of practice guidelines.

(iii) Improving performance.

(iv) Systematic and periodic follow-up on the effect of the interventions.

(2) For each project, the organization must assess performance under the plan using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.

(3) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(4) Interventions must achieve demonstrable improvement.

(5) The organization must report the status and results of each project to CMS as requested.

(e) *Requirements for MA regional plans and MA local plans that are PPO plans as defined in this section*—(1) *Definition of local preferred provider organization plan.* For purposes of this section, the term local preferred provider organization (PPO) plan means an MA plan that—

(i) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(ii) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and

(iii) Is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(2) MA organizations offering an MA regional plan or local PPO plan as defined in this section must:

(i) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Evaluate the continuity and coordination of care furnished to enrollees.

(iii) If the organization uses written protocols for utilization review, the organization must—

(A) Base those protocols on current standards of medical practice; and

(B) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans*—(1) *Health information.* For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to CMS.

(2) *Program review.* For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

[70 FR 4723, Jan. 28, 2005, as amended at 70 FR 52026, Sept. 1, 2005]

EFFECTIVE DATE NOTE: At 70 FR 52026, Sept. 1, 2005, in § 422.152, paragraphs (a)(1) and (c) were suspended, effective September 1, 2005 through January 1, 2006.

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An MA organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The MA organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization used the standards approved by CMS for the purposes of assessing the MA organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) Quality improvement.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

(7) Part D prescription drug benefit programs that are offered by MA programs.

(c) *Effective date of deemed status.* The date on which the organization is deemed to meet the applicable requirements is the later of the following:

(1) The date on which the accreditation organization is approved by CMS.

(2) The date the MA organization is accredited by the accreditation organization.

(d) *Obligations of deemed MA organizations.* An MA organization deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of an MA organization's deemed status for any of the following reasons:

(1) CMS determines, on the basis of its own investigation, that the MA organization does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the MA organization.

(3) The MA organization fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* CMS retains the authority to initiate enforcement action against any MA organization that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000; 70 FR 4724, Jan. 28, 2005]

EFFECTIVE DATE NOTE: At 70 FR 52026, Sept. 1, 2005, in § 422.156, paragraph (b)(7) was suspended, effective September 1, 2005 through January 1, 2006.

§ 422.157 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

(1) In accrediting MA organizations, it applies and enforces standards that are at least as stringent as Medicare requirements with respect to the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 422.158.

(3) It ensures that:

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity.

(ii) The majority of the membership of its governing body is not comprised of managed care organizations or their representatives.

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment*—(1) *Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS will use in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final FEDERAL REGISTER notice indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed MA organizations.

(iv) Information about any MA organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal or revision of the MA organization's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit to CMS—

(i) An acknowledgment of CMS's notification of the change;

(ii) A revised cross-walk reflecting the new requirements; and

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the time-frames specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited MA organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited MA organizations.

(6) Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization.

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results—

(i) Indicate a 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Indicate any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) Indicate that, irrespective of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process such that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating survey results or the accreditation status decision making process, and interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not

meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming based on accreditation no longer guarantees that the MA organization meets the MA requirements, and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 422.156 or § 422.158.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000]

§ 422.158 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials. (When reapplying for approval, the organization need furnish only the particular information and materials requested by CMS.)

(1) The types of MA plans that it would review as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including—

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited MA organizations of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) The education and experience requirements surveyors must meet;

(iii) The content and frequency of the in-service training provided to survey personnel;

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) The organization's policies and practice with respect to the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full, partial) and categories (for example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type

and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval must also submit the following supporting documentation:

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 422.157(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents, and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval has been granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received notice of denial of its request for approval may request reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based;

(ii) Can demonstrate that the MA organizations that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS's denial of its request for approval may not submit a new request until the reconsideration is administratively final.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40324, June 29, 2000]

Subpart E—Relationships With Providers

SOURCE: 63 FR 35085, June 26, 1998, unless otherwise noted.

§ 422.200 Basis and scope.

This subpart is based on sections 1852(a)(1), (a)(2), (b)(2), (c)(2)(D), (j), and (k) of the Act; section 1859(b)(2)(A) of the Act; and the general authority under 1856(b) of the Act requiring the establishment of standards. It sets forth the requirements and standards for the MA organization's relationships with providers including physicians, other health care professionals, institutional providers and suppliers, under contracts or arrangements or deemed contracts under MA private fee-for-

service plans. This subpart also contains some requirements that apply to noncontracting providers.

§ 422.202 Participation procedures.

(a) *Notice and appeal rights.* An MA organization that operates a coordinated care plan or network MSA plan must provide for the participation of individual physicians, and the management and members of groups of physicians, through reasonable procedures that include the following:

(1) Written notice of rules of participation including terms of payment, credentialing, and other rules directly related to participation decisions.

(2) Written notice of material changes in participation rules before the changes are put into effect.

(3) Written notice of participation decisions that are adverse to physicians.

(4) A process for appealing adverse participation procedures, including the right of physicians to present information and their views on the decision. In the case of termination or suspension of a provider contract by the MA organization, this process must conform to the rules in § 422.202(d).

(b) *Consultation.* The MA organization must establish a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures and ensure that the following standards are met:

(1) Practice guidelines and utilization management guidelines—

(i) Are based on reasonable medical evidence or a consensus of health care professionals in the particular field;

(ii) Consider the needs of the enrolled population;

(iii) Are developed in consultation with contracting physicians; and

(iv) Are reviewed and updated periodically.

(2) The guidelines are communicated to providers and, as appropriate, to enrollees.

(3) Decisions with respect to utilization management, enrollee education, coverage of services, and other areas in which the guidelines apply are consistent with the guidelines.

(c) *Subcontracted groups.* An MA organization that operates an MA plan through subcontracted physician groups must provide that the participation procedures in this section apply equally to physicians within those subcontracted groups.

(d) *Suspension or termination of contract.* An MA organization that operates a coordinated care plan or network MSA plan providing benefits through contracting providers must meet the following requirements:

(1) *Notice to physician.* An MA organization that suspends or terminates an agreement under which the physician provides services to MA plan enrollees must give the affected individual written notice of the following:

(i) The reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the MA organization.

(ii) The affected physician's right to appeal the action and the process and timing for requesting a hearing.

(2) *Composition of hearing panel.* The MA organization must ensure that the majority of the hearing panel members are peers of the affected physician.

(3) *Notice to licensing or disciplinary bodies.* An MA organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care must give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

(4) *Timeframes.* An MA organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

[64 FR 7981, Feb. 17, 1999, as amended at 65 FR 40324, June 29, 2000; 68 FR 50857, Aug. 22, 2003; 70 FR 4724, Jan. 28, 2005]

§ 422.204 Provider selection and credentialing.

(a) *General rule.* An MA organization must have written policies and procedures for the selection and evaluation of providers. These policies must conform with the credential and recredentialing requirements set forth in paragraph (b) of this section and with the antidiscrimination provisions set forth in § 422.205.

(b) *Basic requirements*. An MA organization must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements that—

(1) For providers (other than physicians and other health care professionals) requires determination, and redetermination at specified intervals, that each provider is—

(i) Licensed to operate in the State, and in compliance with any other applicable State or Federal requirements; and

(ii) Reviewed and approved by an accrediting body, or meets the standards established by the organization itself;

(2) For physicians and other health care professionals, including members of physician groups, covers—

(i) Initial credentialing that includes written application, verification of licensure or certification from primary sources, disciplinary status, eligibility for payment under Medicare, and site visits as appropriate. The application must be signed and dated and include an attestation by the applicant of the correctness and completeness of the application and other information submitted in support of the application;

(ii) Recredentialing at least every 3 years that updates information obtained during initial credentialing, considers performance indicators such as those collected through quality improvement programs, utilization management systems, handling of grievances and appeals, enrollee satisfaction surveys, and other plan activities, and that includes an attestation of the correctness and completeness of the new information; and

(iii) A process for consulting with contracting health care professionals with respect to criteria for credentialing and recredentialing.

(3) Specifies that basic benefits must be provided through, or payments must be made to, providers and suppliers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of ''provider of services'' in section 1861(u) of the Act, basic benefits may only be provided through these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare.

(4) Ensures compliance with the requirements at § 422.752(a)(8) that prohibit employment or contracts with individuals (or with an entity that employs or contracts with such an individual) excluded from participation under Medicare and with the requirements at § 422.220 regarding physicians and practitioners who opt out of Medicare.

[65 FR 40324, June 29, 2000, as amended at 66 FR 47413, Sept. 12, 2001; 70 FR 4724, Jan. 28, 2005]

§ 422.205 Provider antidiscrimination rules.

(a) *General rule*. Consistent with the requirements of this section, the policies and procedures concerning provider selection and credentialing established under § 422.204, and with the requirement under § 422.100(c) that all Medicare-covered services be available to MA plan enrollees, an MA organization may select the practitioners that participate in its plan provider networks. In selecting these practitioners, an MA organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under State law, solely on the basis of the license or certification. If an MA organization declines to include a given provider or group of providers in its network, it must furnish written notice to the effected provider(s) of the reason for the decision.

(b) *Construction*. The prohibition in paragraph (a)(1) of this section does not preclude any of the following by the MA organization:

(1) Refusal to grant participation to health care professionals in excess of the number necessary to meet the needs of the plan's enrollees (except for MA private-fee-for-service plans, which may not refuse to contract on this basis).

(2) Use of different reimbursement amounts for different specialties or for different practitioners in the same specialty.

(3) Implementation of measures designed to maintain quality and control

costs consistent with its responsibilities.

[65 FR 40324, June 29, 2000]

§ 422.206 Interference with health care professionals' advice to enrollees prohibited.

(a) *General rule.* (1) An MA organization may not prohibit or otherwise restrict a health care professional, acting within the lawful scope of practice, from advising, or advocating on behalf of, an individual who is a patient and enrolled under an MA plan about—

(i) The patient's health status, medical care, or treatment options (including any alternative treatments that may be self-administered), including the provision of sufficient information to the individual to provide an opportunity to decide among all relevant treatment options;

(ii) The risks, benefits, and consequences of treatment or non-treatment; or

(iii) The opportunity for the individual to refuse treatment and to express preferences about future treatment decisions.

(2) Health care professionals must provide information regarding treatment options in a culturally-competent manner, including the option of no treatment. Health care professionals must ensure that individuals with disabilities have effective communications with participants throughout the health system in making decisions regarding treatment options.

(b) *Conscience protection.* The general rule in paragraph (a) of this section does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—

(1) Objects to the provision of that service on moral or religious grounds; and

(2) Through appropriate written means, makes available information on these policies as follows:

(i) To CMS, with its application for a Medicare contract, within 10 days of submitting its bid proposal or, for policy changes, in accordance with § 422.80 (concerning approval of marketing materials and election forms) and with § 422.111.

(ii) To prospective enrollees, before or during enrollment.

(iii) With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice of such change within 90 days after adopting the policy at issue; however, under § 422.111(d), notice of such a change must be given in advance.

(c) *Construction.* Nothing in paragraph (b) of this section may be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(d) *Sanctions.* An MA organization that violates the prohibition of paragraph (a) of this section or the conditions in paragraph (b) of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 52026, Sept. 1, 2005]

§ 422.208 Physician incentive plans: requirements and limitations.

(a) *Definitions.* In this subpart, the following definitions apply:

Bonus means a payment made to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold.

Capitation means a set dollar payment per patient per unit of time (usually per month) paid to a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the physician's own services, referral services, or all medical services.

Physician group means a partnership, association, corporation, individual practice association, or other group of physicians that distributes income from the practice among members. An individual practice association is defined as a physician group for this section only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement to pay a physician or physician group that may directly or indirectly have the effect of

reducing or limiting the services provided to any plan enrollee.

Potential payments means the maximum payments possible to physicians or physician groups including payments for services they furnish directly, and additional payments based on use and costs of referral services, such as withholds, bonuses, capitation, or any other compensation to the physician or physician group. Bonuses and other compensation that are not based on use of referrals, such as quality of care furnished, patient satisfaction or committee participation, are not considered payments in the determination of substantial financial risk.

Referral services means any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not furnish directly.

Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a physician incentive plan without being at substantial financial risk. This is set at 25 percent risk.

Substantial financial risk, for purposes of this section, means risk for referral services that exceeds the risk threshold.

Withhold means a percentage of payments or set dollar amounts deducted from a physician's service fee, capitation, or salary payment, and that may or may not be returned to the physician, depending on specific predetermined factors.

(b) *Applicability*. The requirements in this section apply to an MA organization and any of its subcontracting arrangements that utilize a physician incentive plan in their payment arrangements with individual physicians or physician groups. Subcontracting arrangements may include an intermediate entity, which includes but is not limited to, an individual practice association that contracts with one or more physician groups or any other organized group such as those specified in § 422.4.

(c) *Basic requirements*. Any physician incentive plan operated by an MA organization must meet the following requirements:

(1) The MA organization makes no specific payment, directly or indirectly, to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to any particular enrollee. Indirect payments may include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section.

(3) For all physician incentive plans, the MA organization provides to CMS the information specified in § 422.210.

(d) *Determination of substantial financial risk*—(1) *Basis*. Substantial financial risk occurs when risk is based on the use or costs of referral services, and that risk exceeds the risk threshold. Payments based on other factors, such as quality of care furnished, are not considered in this determination.

(2) *Risk threshold*. The risk threshold is 25 percent of potential payments.

(3) *Arrangements that cause substantial financial risk*. The following incentive arrangements cause substantial financial risk within the meaning of this section, if the physician's or physician group's patient panel size is not greater than 25,000 patients, as shown in the table at paragraph (f)(2)(iii) of this section:

(i) Withholds greater than 25 percent of potential payments.

(ii) Withholds less than 25 percent of potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of potential payments.

(iii) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(iv) Withholds plus bonuses if the withholds plus bonuses equal more than 25 percent of potential payments. The threshold bonus percentage for a particular withhold percentage may be

calculated using the formula—Withhold % = −0.75 (Bonus %) +25%.

(v) Capitation arrangements, if—

(A) The difference between the maximum potential payments and the minimum potential payments is more than 25 percent of the maximum potential payments;

(B) The maximum and minimum potential payments are not clearly explained in the contract with the physician or physician group.

(vi) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(e) *Prohibition for private MA fee-for-service plans.* An MA fee-for-service plan may not operate a physician incentive plan.

(f) *Stop-loss protection requirements*—(1) *Basic rule.* The MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with the following requirements:

(2) *Specific requirements.* (i) Aggregate stop-loss protection must cover 90 percent of the costs of referral services that exceed 25 percent of potential payments.

(ii) For per-patient stop-loss protection if the stop-loss protection provided is on a per-patient basis, the stop-loss limit (deductible) per patient must be determined based on the size of the patient panel and may be a combined policy or consist of separate policies for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (g) of this section.

(iii) Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient deductible limit. The per-patient stop-loss deductible limits are as follows:

Panel size	Single combined deductible	Separate institutional deductible	Separate professional deductible
1–1,000	$6,000	$10,000	$3,000
1,001–5,000	30,000	40,000	10,000
5,001–8,000	40,000	60,000	15,000
8,001–10,000	75,000	100,000	20,000
10,001–25,000	150,000	200,000	25,000
>25,000	(1)	(1)	(1)

[1] None.

(g) *Pooling of patients.* Any entity that meets the pooling conditions of this section may pool commercial, Medicare, and Medicaid enrollees or the enrollees of several MA organizations with which a physician or physician group has contracts. The conditions for pooling are as follows:

(1) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group.

(2) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled.

(3) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled.

(4) The distribution of payments to physicians from the risk pool is not calculated separately by patient category.

(5) The terms of the risk borne by the physician or physician group are comparable for all categories of patients being pooled.

(h) *Sanctions.* An MA organization that fails to comply with the requirements of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 4724, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005]

§ 422.210 Assurances to CMS.

(a) Assurances to CMS. Each organization will provide assurance satisfactory to the Secretary that the requirements of § 422.208 are met.

(b) Disclosure to Medicare Beneficiaries. Each MA organization must provide the following information to

any Medicare beneficiary who requests it:

(1) Whether the MA organization uses a physician incentive plan that affects the use of referral services.

(2) The type of incentive arrangement.

(3) Whether stop-loss protection is provided.

[70 FR 52026, Sept. 1, 2005]

§ 422.212 Limitations on provider indemnification.

An MA organization may not contract or otherwise provide, directly or indirectly, for any of the following individuals, organizations, or entities to indemnify the organization against any civil liability for damage caused to an enrollee as a result of the MA organization's denial of medically necessary care:

(a) A physician or health care professional.

(b) Provider of services.

(c) Other entity providing health care services.

(d) Group of such professionals, providers, or entities.

§ 422.214 Special rules for services furnished by noncontract providers.

(a) *Services furnished by non-section 1861(u) providers.* (1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

(2) Any statutory provisions (including penalty provisions) that apply to payment for services furnished to a beneficiary not enrolled in an MA plan also apply to the payment described in paragraph (a)(1) of this section.

(b) Services furnished by section 1861(u) providers of service. Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts (less any payments under § 412.105(g) and § 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.76 concerns calculating payment for direct medical education costs.)

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 4724, Jan. 28, 2005; 70 FR 47490, Aug. 12, 2005]

§ 422.216 Special rules for MA private fee-for-service plans.

(a) *Payment to providers*—(1) *Payment rate.* (i) The MA organization must establish uniform payment rates for items and services that apply to all contracting providers, regardless of whether the contract is signed or deemed under paragraph (f) of this section.

(ii) Contracting providers must be reimbursed on a fee-for-service basis.

(iii) The MA organization must make information on its payment rates available to providers that furnish services that may be covered under the MA private fee-for-service plan.

(2) *Payment to contract providers.* For each service, the MA organization pays a contract provider (including one deemed to have a contract) an amount that is equal to the payment rate under paragraph (a)(1) of this section minus any applicable cost-sharing.

(3) *Noncontract providers.* The organization pays for services of noncontract providers in accordance with § 422.100(b)(2).

(4) *Service furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment mounts for services furnished to a beneficiary enrolled in an MA private fee-for-service plan must accept as payment in full the amounts (less any payments under §§ 412.105(g) and 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

(b) *Charges to enrollees*—(1) *Contract providers.* (i) Contract providers and ''deemed'' contract providers may

charge enrollees no more than the cost-sharing and, subject to the limit in paragraph (b)(1)(ii) of this section, balance billing amounts that are permitted under the plan, and these amounts must be the same for ''deemed'' contract providers as for those that have signed contracts in effect.

(ii) The organization may permit balance billing no greater than 15 percent of the payment rate established under paragraph (a)(1) of this section.

(iii) The MA organization must specify the amount of cost-sharing and balance billing in its contracts with providers and these amounts must be the same for ''deemed'' contract providers as for those that have signed contracts in effect.

(iv) The MA organization is subject to intermediate sanctions under § 422.752(a)(7), under the rules in subpart O of this part, if it fails to enforce the limit specified in paragraph (b)(1)(i) of this section.

(2) *Noncontract providers.* A noncontract provider may not collect from an enrollee more than the cost-sharing established by the MA private fee-for-service plan as specified in § 422.256(b)(3), unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter.

(c) *Enforcement of limit*—(1) *Contract providers.* An MA organization that offers an MA fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section.

(2) *Noncontract providers.* An MA organization that offers an MA private fee-for-service plan must monitor the amount collected by noncontract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section, unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter. The MA organization must develop and document violations specified in instructions and must forward documented cases to CMS.

(d) *Information on enrollee liability*—(1) *General information.* An MA organization that offers an MA fee-for-service plan must provide to plan enrollees, for each claim filed by the enrollee or the provider that furnished the service, an appropriate explanation of benefits. The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, copayment, and balance billing.

(2) *Advance notice for hospital services.* In its terms and conditions of payment to hospitals, the MA organization must require the hospital, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to not less than $500—

(i) Notice that balance billing is permitted for those services;

(ii) A good faith estimate of the likely amount of balance billing, based on the enrollees presenting condition; and

(iii) The amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount.

(e) *Coverage determinations.* The MA organization must make coverage determinations in accordance with subpart M of this part.

(f) *Rules describing deemed contract providers.* Any provider furnishing health services, except for emergency services furnished in a hospital pursuant to § 489.24 of this chapter, to an enrollee in an MA private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, is treated as having a contract in effect and is subject to the limitations of this section that apply to contract providers if the following conditions are met:

(1) The services are covered under the plan and are furnished—

(i) To an enrollee of an MA fee-for-service plan; and

(ii) Provided by a provider including a provider of services (as defined in section 1861(u) of the Act) that does not have in effect a signed contract with the MA organization.

(2) Before furnishing the services, the provider—

(i) Was informed of the individual's enrollment in the plan; and

(ii) Was informed (or given a reasonable opportunity to obtain information) about the terms and conditions of payment under the plan, including the information described in § 422.202(a)(1).

(3) The information was provided in a manner that was reasonably designed to effect informed agreement and met the requirements of paragraphs (g) and (h) of this section.

(g) *Enrollment information.* Enrollment information was provided by one of the following methods or a similar method:

(1) Presentation of an enrollment card or other document attesting to enrollment.

(2) Notice of enrollment from CMS, a Medicare intermediary or carrier, or the MA organization itself.

(h) *Information on payment terms and conditions.* Information on payment terms and conditions was made available through either of the following methods:

(1) The MA organization used postal service, electronic mail, FAX, or telephone to communicate the information to one of the following:

(i) The provider.

(ii) The employer or billing agent of the provider.

(iii) A partnership of which the provider is a member.

(iv) Any party to which the provider makes assignment or reassigns benefits.

(2) The MA organization has in effect a procedure under which—

(i) Any provider furnishing services to an enrollee in an MA private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, can receive instructions on how to request the payment information;

(ii) The organization responds to the request before the entity furnishes the service; and

(iii) The information the organization provides includes the following:

(A) Billing procedures.

(B) The amount the organization will pay towards the service.

(C) The amount the provider is permitted to collect from the enrollee.

(D) The information described in § 422.202(a)(1).

(3) Announcements in newspapers, journals, or magazines or on radio or television are not considered communication of the terms and conditions of payment.

(i) *Provider credentialing requirements.* Contracts with providers must provide that, in order to be paid to provide services to plan enrollees, providers must meet the requirements specified in § 422.204(a)(1) and (a)(1)(iii).

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 47490, Aug. 12, 2005; 70 FR 52056, Sept. 1, 2005]

§ 422.220 Exclusion of services furnished under a private contract.

An MA organization may not pay, directly or indirectly, on any basis, for services (other than emergency or urgently needed services as defined in § 422.2) furnished to a Medicare enrollee by a physician (as defined in section 1861(r)(1) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare carrier an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries. An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner who has not signed a private contract with the beneficiary.

Subpart F-Submission of Bids, Premiums, and Related Information and Plan Approval

SOURCE: 70 FR 4725, Jan. 28, 2005, unless otherwise noted.

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from section 1853 and section 1858 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, and negotiation and approval of bids by CMS.

§ 422.252 Terminology.

Annual MA capitation rate means a county payment rate for an MA local area (county) for a calendar year. The

terms ''per capita rate'' and ''capitation rate'' are used interchangeably to refer to the annual MA capitation rate.

MA local area means a payment area consisting of county or equivalent area specified by CMS.

MA monthly basic beneficiary premium means the premium amount an MA plan (except an MSA plan) charges an enrollee for benefits under the original Medicare fee-for-service program option (if any), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of benefits under the original Medicare program through an MSA plan, as set forth at § 422.254(e).

MA monthly prescription drug beneficiary premium is the MA-PD plan base beneficiary premium, defined at section 1860D–13(a)(2) of the Act, as adjusted to reflect the difference between the plan's bid and the national average bid (as described in § 422.256(c)) less the amount of rebate the MA-PD plan elects to apply, as described at § 422.266(b)(2).

MA monthly supplemental beneficiary premium is the portion of the plan bid attributable to mandatory and/or optional supplemental health care benefits described under § 422.102, less the amount of beneficiary rebate the plan elects to apply to a mandatory supplemental benefit, as described at § 422.266(b)(1).

MA-PD plan means an MA local or regional plan that provides prescription drug coverage under Part D of Title XVIII of the Social Security Act.

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits;

(2) The amount for coverage of basic prescription drug benefits under Part D (if any); and

(3) The amount for provision of supplemental health care benefits (if any).

Plan basic cost sharing means cost sharing that would be charged by a plan for benefits under the original Medicare FFS program option before any reductions resulting from mandatory supplemental benefits.

Unadjusted MA area-specific non-drug monthly benchmark amount means, for local MA plans serving one county, the county capitation rate CMS publishes annually, and for local MA plans serving multiple counties it is the weighted average of county rates in a plan's service area, weighted by the plan's projected enrollment per county.

Unadjusted MA region-specific non-drug monthly benchmark amount means, for MA regional plans, the amount described at § 422.258(b).

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of original Medicare benefits to an MA eligible beneficiary with a nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c).

63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005]

§ 422.254 Submission of bids.

(a) *General rules.* (1) Not later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section and, for plans with rebates as described at § 422.266(a), the MA organization must provide the information required in paragraph (d) of this section.

(2) CMS has the authority to determine whether and when it is appropriate to apply the bidding methodology described in this section to ESRD MA enrollees.

(3) If the bid submission described in paragraphs (a)(1) and (2) of this section is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

(b) *Bid requirements.* (1) The monthly aggregate bid amount submitted by an MA organization for each plan is the organization's estimate of the revenue required for the following categories for providing coverage to an MA eligible beneficiary with a national average risk profile for the factors described in § 422.308(c):

(i) The unadjusted MA statutory non-drug monthly bid amount, which is the MA plan's estimated average monthly required revenue for providing benefits under the original Medicare fee-for-service program option (as defined in § 422.252).

(ii) The amount to provide basic prescription drug coverage, if any (defined at section 1860D–2(a)(3) of the Act).

(iii) The amount to provide supplemental health care benefits, if any.

(2) Each bid is for a uniform benefit package for the service area.

(3) Each bid submission must contain all estimated revenue required by the plan, including administrative costs and return on investment.

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at § 422.101(d).

(c) *Information required for coordinated care plans and MA private fee-for-service plans.* MA organizations' submission of bids for coordinated care plans, including regional MA plans and specialized MA plans for special needs beneficiaries (described at § 422.4(a)(1)(iv)), and for MA private fee-for-service plans must include the following information:

(1) The plan type for each plan.

(2) The monthly aggregate bid amount for the provision of all items and services under the plan, as defined in § 422.252 and discussed in paragraph (a) of this section.

(3) The proportions of the bid amount attributable to-

(i) The provision of benefits under the original Medicare fee-for-service program option (as defined at § 422.100(c));

(ii) The provision of basic prescription drug coverage (as defined at section 1860D–2(a)(3) of the Act; and

(iii) The provision of supplemental health care benefits (as defined § 422.102).

(4) The projected number of enrollees in each MA local area used in calculation of the bid amount, and the enrollment capacity, if any, for the plan.

(5) The actuarial basis for determining the amount under paragraph (c)(2) of this section, the proportions under paragraph (c)(3) of this section, the amount under paragraph (b)(4) of this section, and additional information as CMS may require to verify actuarial bases and the projected number of enrollees.

(6) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of the deductibles, coinsurance, and copayments.

(7) For qualified prescription drug coverage, the information required under section 1860D–11(b) of the Act with respect to coverage.

(8) For the purposes of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit the following information developed using the appropriate actuarial bases.

(i) Projected allowable costs (defined in § 422.458(a)).

(ii) The portion of projected allowable costs attributable to administrative expenses incurred in providing these benefits.

(iii) The total projected costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of costs that is attributable to administrative expenses.

(9) For regional plans, as determined by CMS, the relative cost factors for the counties in a plan's service area,

for the purposes of adjusting payment under § 422.308(d) for intra-area variations in an MA organization's local payment rates.

(d) *Beneficiary rebate information.* In the case of a plan required to provide a monthly rebate under § 422.266 for a year, the MA organization offering the plan must inform CMS how the plan will distribute the beneficiary rebate among the options described at § 422.266(b).

(e) *Information required for MSA plans.* MA organizations intending to offer MA MSA plans must submit—

(1) The enrollment capacity (if any) for the plan;

(2) The amount of the MSA monthly premium for basic benefits under the original Medicare fee-for-service program option;

(3) The amount of the plan deductible; and

(4) The amount of the beneficiary supplemental premium, if any.

(f) Separate bids must be submitted for Part A and Part B enrollees and Part B-only enrollees for each MA plan offered.

63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005]

§ 422.256 Review, negotiation, and approval of bids.

(a) *Authority.* Subject to paragraphs (a)(2), (d), and (e) of this section, CMS has the authority to review the aggregate bid amounts submitted under § 422.252 and conduct negotiations with MA organizations regarding these bids (including the supplemental benefits) and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits.

(1) When negotiating bid amounts and proportions, CMS has authority similar to that provided the Director of the Office of Personnel Management for negotiating health benefits plans under 5 U.S.C. chapter 89.

(2) *Noninterference.* (i) In carrying out Parts C and D under this title, CMS may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services.

(ii) CMS may not require a particular price structure for payment under such a contract, with the exception of payments to Federally qualified health centers as set forth at § 422.316.

(b) *Standards of bid review.* Subject to paragraphs (d) and (e) of this section, CMS can only accept bid amounts or proportions described in paragraph (a) of this section if CMS determines the following standards have been met:

(1) The bid amount and proportions are supported by the actuarial bases provided by MA organizations under § 422.254.

(2) The bid amount and proportions reasonably and equitably reflects the plan's estimated revenue requirements for providing the benefits under that plan, as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act.

(3) *Limitation on enrollee cost sharing.* For coordinated care plans (including regional MA plans and specialized MA plans) and private fee-for-service plans (other than MSA plans):

(i) The actuarial value of plan basic cost sharing, reduced by any supplemental benefits, may not exceed—

(ii) The actuarial value of deductibles, coinsurance, and copayments that would be applicable for the benefits to individuals entitled to benefits under Part A and enrolled under Part B in the plan's service area with a national average risk profile for the factors described in § 422.308(c) if they were not members of an MA organization for the year, except that cost sharing for non-network Medicare services in a regional MA plan is not counted under the amount described in paragraph (b)(2)(i) of this section.

(c) *Negotiation process.* The negotiation process may include the resubmission of information to allow MA organizations to modify their initial bid submissions to account for the outcome of CMS' regional benchmark calculations required under § 422.258(c) and the outcome of CMS' calculation of the national average monthly bid amount required under section 1860D–13(a)(4) of the Act.

(d) *Exception for private fee-for-service plans.* For private fee-for-service plans defined at § 422.4(a)(3), CMS will not review, negotiate, or approve the bid amount, proportions of the bid, or the

amounts of the basic beneficiary premium and supplemental premium.

(e) *Exception for MSA plans.* CMS does not review, negotiate, or approve amounts submitted with respect to MA MSA plans, except to determine that the deductible does not exceed the statutory maximum, defined at § 422.103(d).

63 FR 35085, June 26, 1998, as amended at 70 FR 52026, Sept. 1, 2005]

§ 422.258 Calculation of benchmarks.

(a) The term ''MA area-specific non-drug monthly benchmark amount'' means, for a month in a year:

(1) *For MA local plans with service areas entirely within a single MA local area*, 1/12th of the annual MA capitation rate (described at § 422.306) for the area, adjusted as appropriate for the purpose of risk adjustment.

(2) *For MA local plans with service areas including more than one MA local area*, an amount equal to the weighted average of annual capitation rates for each local area (county) in the plan's service area, using as weights the projected number of enrollees in each MA local area that the plan used to calculate the bid amount, and adjusted as appropriate for the purpose of risk adjustment.

(b) For MA regional plans, the term ''MA region-specific non-drug monthly benchmark amount'' is:

(1) The sum of two components: the statutory component (based on a weighted average of local benchmarks in the region, as described in paragraph (c)(3) of this section; and the plan bid component (based on a weighted average of regional plan bids in the region as described in paragraph (c)(4) of this section).

(2) Announced before November 15 of each year, but after CMS has received the plan bids.

(c) *Calculation of MA regional non-drug benchmark amount.* CMS calculates the monthly regional non-drug benchmark amount for each MA region as follows:

(1) *Reference month.* For all calculations that follow, CMS will determine the number of MA eligible individuals in each local area, in each region, and nationally as of the reference month, which is a month in the previous calendar year CMS identifies.

(2) *Statutory market share.* CMS will determine the statutory national market share percentage as the proportion of the MA eligible individuals nationally who were not enrolled in an MA plan.

(3) *Statutory component of the region-specific benchmark.* (i) CMS calculates the unadjusted region-specific non-drug amount by multiplying the county capitation rate by the county's share of the MA eligible individuals residing in the region (the number of MA eligible individuals in the county divided by the number of MA eligible individuals in the region), and then adding all the enrollment-weighted county rates to a sum for the region.

(ii) CMS then multiplies the unadjusted region-specific non-drug amount from paragraph (c)(3)(i) of this section by the statutory market share to determine the statutory component of the regional benchmark.

(4) *Plan-bid component of the region-specific benchmark.* For each regional plan offered in a region, CMS will multiply the plan's unadjusted region-specific non-drug bid amount by the plan's share of enrollment (as determined under paragraph (c)(5) of this section) and then sum these products across all plans offered in the region. CMS then multiples this by 1 minus the statutory market share to determine the plan-bid component of the regional benchmark.

(5) *Plan's share of enrollment.* CMS will calculate the plan's share of MA enrollment in the region as follows:

(i) In the first year that any MA regional plan is being offered in an MA region, and more than one MA regional plan is being offered, CMS will determine each regional plan's share of enrollment based on one of two possible approaches. CMS may base this factor on equal division among plans, so that each plan's share will be 1 divided by the number of plans offered. Alternatively, CMS may base this factor on each regional plan's estimate of projected enrollment. Plan enrollment projections are subject to review and adjustment by CMS to assure reasonableness.

(ii) If two or more regional plans are offered in a region and were offered in the reference month: The plan's share of enrollment will be the number of MA

eligible individuals enrolled in the plan divided by the number of MA eligible individuals enrolled in all of the plans in the region, as of the reference month.

(iii) If a single regional plan is being offered in the region: The plan's share of enrollment is equal to 1.

§ 422.262 Beneficiary premiums.

(a) Determination of MA monthly basic beneficiary premium. (1) For an MA plan with an unadjusted statutory non-drug bid amount that is less than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is zero.

(2) For an MA plan with an unadjusted statutory non-drug bid amount that is equal to or greater than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is the amount by which (if any) the bid amount exceeds the benchmark amount. All approved basic premiums must be charged; they cannot be waived.

(b) Consolidated monthly premiums. Except as specified in paragraph (b)(2) of this section, MA organizations must charge enrollees a consolidated monthly MA premium.

(1) The consolidated monthly premium for an MA plan (other than a MSA plan) is the sum of the MA monthly basic beneficiary premium (if any), the MA monthly supplementary beneficiary premium (if any), and the MA monthly prescription drug beneficiary premium (if any).

(2) *Special rule for MSA plans.* For an individual enrolled in an MSA plan offered by an MA organization, the monthly beneficiary premium is the supplemental premium (if any).

(c) *Uniformity of premiums*—(1) *General rule.* Except as permitted for supplemental premiums pursuant to § 422.106(d), for MA contracts with employers and labor organizations, the MA monthly bid amount submitted under § 422.254, the MA monthly basic beneficiary premium, the MA monthly supplemental beneficiary premium, the MA monthly prescription drug premium, and the monthly MSA premium of an MA organization may not vary among individuals enrolled in an MA plan (or segment of the plan as provided for local MA plans under paragraph (c)(2) of this section). In addition, the MA organization cannot vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any) among individuals enrolled in an MA plan (or segment of the plan).

(2) *Segmented service area option.* An MA organization may apply the uniformity requirements in paragraph (c)(1) of this section to segments of an MA local plan service area (rather than to the entire service area) as long as such a segment is composed of one or more MA payment areas. The information specified under § 422.254 is submitted separately for each segment. This provision does not apply to MA regional plans.

(d) *Monetary inducement prohibited.* An MA organization may not provide for cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

(e) *Timing of payments.* The MA organization must permit payments of MA monthly basic and supplemental beneficiary premiums and monthly prescription drug beneficiary premiums on a monthly basis and may not terminate coverage for failure to make timely payments except as provided in § 422.74(b).

(f) *Beneficiary payment options.* An MA organization must permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the organization through-

(1) Withholding from the enrollee's Social Security benefit payments, or benefit payments by the Railroad Retirement Board or the Office of Personnel Management, in the manner that the Part B premium is withheld;

(2) An electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account);

(3) According to other means that CMS may specify, including payment by an employer or under employment-based retiree health coverage on behalf of an employee, former employee (or dependent), or by other third parties such as a State.

(i) Regarding the option in paragraph (f)(1) of this section, MA organizations

may not impose a charge on beneficiaries for the election of this option.

(ii) An enrollee may opt to make a direct payment of premium to the plan.

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks.*

(1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted plan bid amount for coverage of original Medicare benefits (defined at § 422.254), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of original Medicare benefits by a local MA plan (defined at § 422.258), adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark for coverage of original Medicare benefits amount by a regional MA plan (defined at § 422.258) adjusted using the factors described in paragraph (e) of this section.

(b) *Computation of savings for MA local plans.* The average per capita monthly savings for an MA local plan is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted area-specific non-drug monthly benchmark amount (described in paragraph (a)(2) of this section). Plans with bids equal to or greater than plan benchmarks will have zero savings.

(c) *Risk adjustment factors for determination of savings for local plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (c)(1) or (c)(2) of this section determined for the purpose of calculating savings amounts for MA local plans.

(1) For the purpose of calculating savings for MA local plans CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Statewide average risk adjustment factors, or factors determined on a basis other than plan-specific factors or Statewide average factors.

(2) In the event that CMS applies Statewide average risk adjustment factors, the statewide factor for each State is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA local plans in that State in the previous year. In the case of a State in which no local MA plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable States or applied on a national basis.

(d) *Computation of savings for MA regional plans.* The average per capita monthly savings for an MA regional plan and year is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted region-specific non-drug monthly benchmark amount (described in paragraph (a)(3) of this section), using the risk adjustment factors described in paragraph (e) of this section. Plans with bids equal to or greater than plan benchmarks will have zero savings.

(e) *Risk adjustment factors for determination of savings for regional plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (e)(1)and (e)(2) of this section determined for the purpose of calculating savings amounts for MA regional plans.

(1) For the purpose of calculating savings for MA regional plans, CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Region-wide average risk adjustment factors, or factors determined on a basis other than MA regions.

(2) In the event that CMS applies region-wide average risk adjustment factors, the region-wide factor for each MA region is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA regional plans in that region in the previous year. In the case of a region in which

no regional plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable regions or applied on a national basis.

§ 422.266 Beneficiary rebates.

(a) *General rule.* An MA organization must provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in § 422.264(b) for MA local plans and § 422.264(d) for MA regional plans.

(b) *Form of rebate.* The rebate required under this paragraph must be provided by crediting the rebate amount to one or more of the following:

(1) *Supplemental health care benefits.* MA organizations may apply all or some portion of the rebate for a plan toward payment for non-drug supplemental health care benefits for enrollees as described in § 422.102, which may include the reduction of cost sharing for benefits under original Medicare and additional health care benefits that are not benefits under original Medicare. MA organizations also may apply all or some portion of the rebate for a plan toward payment for supplemental drug coverage described at § 423.104(f)(1)(ii), which may include reduction in cost sharing and coverage of drugs not covered under Part D. The rebate, or portion of rebate, applied toward supplemental benefits may only be applied to a mandatory supplemental benefit, and cannot be used to fund an optional supplemental benefit.

(2) *Payment of premium for prescription drug coverage.* MA organizations that offer a prescription drug benefit may credit some or all of the rebate toward reduction of the MA monthly prescription drug beneficiary premium.

(3) *Payment toward Part B premium.* MA organizations may credit some or all of the rebate toward reduction of the Medicare Part B premium (determined without regard to the application of subsections (b), (h), and (i) of section 1839 of the Act).

(c) *Disclosure relating to rebates.* MA organizations must disclose to CMS information on the amount of the rebate provided, as required at § 422.254(d). MA organizations must distinguish, for each MA plan, the amount of rebate applied to enhance original Medicare benefits from the amount of rebate applied to enhance Part D benefits.

§ 422.270 Incorrect collections of premiums and cost-sharing.

(a) *Definitions.* As used in this section-

(1) Amounts incorrectly collected-

(i) Means amounts that-

(A) Exceed the limits approved under § 422.262;

(B) In the case of an MA private fee-for-service plan, exceed the MA monthly basic beneficiary premium or the MA monthly supplemental premium submitted under § 422.262; and

(C) In the case of an MA MSA plan, exceed the MA monthly beneficiary supplemental premium submitted under § 422.262, or exceed permissible cost sharing amounts after the deductible has been met per § 422.103; and

(ii) Includes amounts collected from an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled.

(2) *Other amounts due* are amounts due for services that were—

(i) Emergency, urgently needed services, or other services obtained outside the MA plan; or

(ii) Initially denied but, upon appeal, found to be services the enrollee was entitled to have furnished by the MA organization.

(b) *Basic commitments.* An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

(c) *Refund methods*—(1) *Lump-sum payment.* The MA organization must use lump-sum payments for the following:

(i) Amounts incorrectly collected that were not collected as premiums.

(ii) Other amounts due.

(iii) All amounts due if the MA organization is going out of business or terminating its MA contract for an MA plan(s).

(2) *Premium adjustment or lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as

well as other charges, the MA organization may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(3) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the MA organization must make the refund in accordance with State law.

(d) *Reduction by CMS.* If the MA organization does not make the refund required under this section by the end of the contract period following the contract period during which an amount was determined to be due to an enrollee, CMS will reduce the premium the MA organization is allowed to charge an MA plan enrollee by the amounts incorrectly collected or otherwise due. In addition, the MA organization would be subject to sanction under subpart O of this part for failure to refund amounts incorrectly collected from MA plan enrollees.

Subpart G—Payments to Medicare Advantage Organizations

SOURCE: 70 FR 4729, Jan. 28, 2005, unless otherwise noted.

§ 422.300 Basis and scope.

This subpart is based on sections 1853, 1854, and 1858 of the Act. It sets forth the rules for making payments to Medicare Advantage (MA) organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), and other payment rules.

See § 422.458 in subpart J for rules on risk sharing payments to MA regional organizations.

§ 422.304 Monthly payments.

(a) *General rules.* Except as provided in paragraph (b) of this section, CMS makes advance monthly payments of the amounts determined under paragraphs (a)(1) and (a)(2) of this section for coverage of original fee-for-service benefits for an individual in an MA payment area for a month.

(1) *Payment of bid for plans with bids below benchmark.* For MA plans that have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays:

(i) The unadjusted MA statutory non-drug monthly bid amount defined in § 422.252, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262; and

(ii) The amount (if any) of the rebate described in paragraph (a)(3) of this section.

(2) *Payment of benchmark for plans with bids at or above benchmark.* For MA plans that do not have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount specified at § 422.258, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262.

(3) *Payment of rebate for plans with bids below benchmarks.* The rebate amount under paragraph (a)(1)(ii) of this section is the amount of the monthly rebate computed under § 422.266(a) for that plan, less the amount (if any) applied to reduce the Part B premium, as provided under § 422.266(b)(3)).

(b) *Separate payment for Federal drug subsidies.* In the case of an enrollee in an MA-PD plan, defined at § 422.252, the MA organization offering such a plan also receives-

(1) Direct and reinsurance subsidy payments for qualified prescription drug coverage, described at section 1860D–15(a) and (b) of the Act (other than payments for fallback prescription drug plans described at section 1860D–11(g)(5) of the Act); and

(2) Reimbursement for premium and cost sharing reductions for low-income

individuals, described at section 1860D–14 of the Act.

(c) *Special rules*—(1) *Enrollees with end-stage renal disease.* (i) For enrollees determined to have end-stage renal disease (ESRD), CMS establishes special rates that are actuarially equivalent to rates in effect before the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(ii) CMS publishes annual changes in these capitation rates no later than the first Monday in April each year, as provided in § 422.312.

(iii) CMS applies appropriate adjustments when establishing the rates, including risk adjustment factors.

(iv) CMS reduces the payment rate for each renal dialysis treatment by the same amount that CMS is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 1881(b)(7) of the Act. These funds are to be used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

(2) *MSA enrollees.* In the case of an MSA plan, CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount for the service area, determined in accordance with § 422.314(c) and subject to risk adjustment as set forth at § 422.308(c), less 1/12 of the annual lump sum amount (if any) CMS deposits to the enrollee's MA MSA.

(3) *RFB plan enrollees.* For RFB plan enrollees, CMS adjusts the capitation payments otherwise determined under this subpart to ensure that the payment level is appropriate for the actuarial characteristics and experience of these enrollees. That adjustment can be made on an individual or organization basis.

(d) *Payment areas*—(1) *General rule.* Except as provided in paragraph (e) of this section—

(i) An MA payment area for an MA local plan is an MA local area defined at § 422.252.

(ii) An MA payment area for an MA regional plan is an MA region, defined at § 422.455(b)(1).

(2) *Special rule for ESRD enrollees.* For ESRD enrollees, the MA payment area is a State or other geographic area specified by CMS.

(e) *Geographic adjustment of payment areas for MA local plans*—(1) *Terminology.* ''Metropolitan Statistical Area'' and ''Metropolitan Division'' mean any areas so designated by the Office of Management and Budget in the Executive Office of the President.

(2) *State request.* A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas for MA local plans for the following calendar year. The chief executive may request any of the following adjustments to the payment area specified in paragraph (c)(1)(i) of this section:

(i) A single statewide MA payment area.

(ii) A metropolitan-based system in which all non-metropolitan areas within the State constitute a single payment area and any of the following constitutes a separate MA payment area:

(A) All portions of each single Metropolitan Statistical Area within the State.

(B) All portions of each Metropolitan Statistical Area within each Metropolitan Division within the State.

(iii) A consolidation of noncontiguous counties.

(3) *CMS response.* In response to the request, CMS makes the payment adjustment requested by the chief executive. This adjustment cannot be requested or made for payments to regional MA plans.

(4) *Budget neutrality adjustment for geographically adjusted payment areas.* If CMS adjusts a State's payment areas in accordance with paragraph (d)(2) of this section, CMS at that time, and each year thereafter, adjusts the capitation rates so that the aggregate Medicare payments do not exceed the aggregate Medicare payments that would have been made to all the State's payments areas, absent the geographic adjustment.

§ 422.306 Annual MA capitation rates.

Subject to adjustments at § 422.308(b) and § 422.308(g), the annual capitation rate for each MA local area is determined under paragraph (a) of this section for 2005 and each succeeding year,

except for years when CMS announces under § 422.312(b) that the annual capitation rates will be determined under paragraph (b) of this section.

(a) *Minimum percentage increase rate.* The annual capitation rate for each MA local area is equal to the minimum percentage increase rate, which is the greater of—

(1) 102 percent of the annual capitation rate for the preceding year; or

(2) The annual capitation rate for the area for the preceding year increased by the national per capita MA growth percentage (defined at § 422.308(a)) for the year, but not taking into account any adjustment under § 422.308(b) for a year before 2004.

(b) *Greater of the minimum percentage increase rate or local area fee-for-service costs.* The annual capitation rate for each MA local area is the greater of—

(1) The minimum percentage increase rate under paragraph (a) of this section; or

(2) The amount determined, no less frequently than every 3 years, to be the adjusted average per capita cost for the MA local area, as determined under section 1876(a)(4) of the Act, based on 100 percent of fee-for-service costs for individuals who are not enrolled in an MA plan for the year, with the following adjustments:

(i) Adjusted as appropriate for the purpose of risk adjustment;

(ii) Adjusted to exclude costs attributable to payments under section 1886(h) of the Act for the costs of direct graduate medical education; and

(iii) Adjusted to include CMS' estimate of the amount of additional per capita payments that would have been made in the MA local area if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.

§ 422.308 Adjustments to capitation rates, benchmarks, bids, and payments.

CMS performs the following calculations and adjustments to determine rates and payments:

(a) *National per capita growth percentage.* The national per capita growth percentage for a year, applied under § 422.306, is CMS' estimate of the rate of growth in per capita expenditures under this title for an individual entitled to benefits under Part A and enrolled under Part B. CMS may make separate estimates for aged enrollees, disabled enrollees, and enrollees who have ESRD.

(b) *Adjustment for over or under projection of national per capita growth percentages.* CMS will adjust the minimum percentage increase rate at § 422.306(a)(2) and the adjusted average per capita cost rate at § 422.306(b)(2) for the previous year to reflect any differences between the projected national per capita growth percentages for that year and previous years, and the current estimates of those percentages for those years. CMS will not make this adjustment for years before 2004.

(c) *Risk adjustment*—(1) *General rule.* CMS will adjust the payment amounts under § 422.304(a)(1), (a)(2), and (a)(3) for age, gender, disability status, institutional status, and other factors CMS determines to be appropriate, including health status, in order to ensure actuarial equivalence. CMS may add to, modify, or substitute for risk adjustment factors if those changes will improve the determination of actuarial equivalence.

(2) *Risk adjustment: Health status*—(i) *Data collection.* To adjust for health status, CMS applies a risk factor based on data obtained in accordance with § 422.310.

(ii) *Implementation.* CMS applies a risk factor that incorporates inpatient hospital and ambulatory risk adjustment data. This factor is phased as follows:

(A) 100 percent of payments for ESRD MA enrollees in 2005 and succeeding years.

(B) 75 percent of payments for aged and disabled enrollees in 2006.

(C) 100 percent of payments for aged and disabled enrollees in 2007 and succeeding years.

(3) *Uniform application.* Except as provided for MA RFB plans under § 422.304(c)(3), CMS applies this adjustment factor to all types of plans.

(d) *Adjustment for intra-area variations.* CMS makes the following adjustments to payments.

(1) *Intra-regional variations.* For payments for an MA regional plan for an MA region, CMS will adjust the payment amount specified at § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the region.

(2) *Intra-service area variations.* For payments to an MA local plan with a service area covering more than one MA local area (county), CMS will adjust the payment amount specified in § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the plan's service area.

(e) *Adjustment relating to risk adjustment: the government premium adjustment.* CMS will adjust payments to an MA plan as necessary to ensure that the sum of CMS' monthly payment made under § 422.304(a) and the plan's monthly basic beneficiary premium equals the unadjusted MA statutory non-drug bid amount, adjusted for risk and for intra-area or intra-regional payment variation.

(f) *Adjustment of payments to reflect number of Medicare enrollees*—(1) *General rule.* CMS adjusts payments retroactively to take into account any difference between the actual number of Medicare enrollees and the number on which it based an advance monthly payment.

(2) *Special rules for certain enrollees.* (i) Subject to paragraph (f)(2)(ii) of this section, CMS may make adjustments, for a period (not to exceed 90 days) that begins when a beneficiary elects a group health plan (as defined in § 411.1010) offered by an MA organization, and ends when the beneficiary is enrolled in an MA plan offered by the MA organization.

(ii) CMS does not make an adjustment unless the beneficiary certifies that, at the time of enrollment under the MA plan, he or she received from the organization the disclosure statement specified in § 422.111.

(g) *Adjustment for national coverage determination (NCD) services and legislative changes in benefits.* If CMS determines that the cost of furnishing an NCD service or legislative change in benefits is significant, as defined in § 422.109, CMS will adjust capitation rates, or make other payment adjustments, to account for the cost of the service or legislative change in benefits. Until the new capitation rates are in effect, the MA organization will be paid for the significant cost NCD service or legislative change in benefits on a fee-for-service basis as provided under § 422.109(b).

(h) *Adjustments to payments to regional MA plans for purposes of risk corridor payments.* For the purpose of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit, after the end of a contract year and before a date CMS specifies, the following information:

(1) Actual allowable costs (defined in § 422.458(a)) for the previous contract year.

(2) The portion of the costs attributable to administrative expenses incurred in providing these benefits.

(3) The total costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of the costs that is attributable to administrative expenses in addition to the administrative expenses described in paragraph (h)(2) of this section.

§ 422.310 Risk adjustment data.

(a) *Definition of risk adjustment data.* Risk adjustment data are all data that are used in the application of a risk adjustment payment model.

(b) *Data collection: Basic rule.* Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

(c) *Sources and extent of data.* (1) To the extent required by CMS, risk adjustment data must account for the following:

(i) Services covered under the original Medicare program.

(ii) Medicare covered services for which Medicare is not the primary payer.

(iii) Other additional or supplemental benefits that the MA organization may provide.

(2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the original Medicare program, even if they participate jointly in the same service.

(d) *Other data requirements.* (1) MA organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards. Alternatively, MA organizations may submit data according to an abbreviated format, as specified by CMS.

(2) The data must be submitted electronically to the appropriate CMS contractor.

(3) MA organizations must obtain the risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the services.

(4) MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.

(e) *Validation of risk adjustment data.* MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data.

(f) *Use of data.* CMS uses the data obtained under this section to determine the risk adjustment factor used to adjust payments, as required under § 422.304(a)(1), (a)(2), and (a)(3). CMS may also use the data for other purposes except for medical records data.

(g) *Deadlines for submission of risk adjustment data.* Risk adjustment factors for each payment year are based on risk adjustment data submitted for services furnished during the 12-month period before the payment year that is specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag that may be changed or eliminated as appropriate.

(1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting services furnished during the 12-month period ending the prior June 30, and the first Friday in March for data reflecting services furnished during the 12-month period ending the prior December 31.

(2) CMS allows a reconciliation process to account for late data submissions. CMS continues to accept risk adjustment data submitted after the March deadline until December 31 of the payment year. After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary. Risk adjustment data that are received after the annual December 31 late data submission deadline will not be accepted for the purposes of reconciliation.

§ 422.312 Announcement of annual capitation rate, benchmarks, and methodology changes.

(a) *Capitation rates*—(1) *Initial announcement.* Not later than the first Monday in April each year, CMS announces to MA organizations and other interested parties the following information for each MA payment area for the following calendar year:

(i) The annual MA capitation rate.

(ii) The risk and other factors to be used in adjusting those rates under § 422.308 for payments for months in that year.

(2) CMS includes in the announcement an explanation of assumptions used and a description of the risk and other factors.

(3) *Regional benchmark announcement.* Before the beginning of each annual, coordinated election period under § 422.62(a)(2), CMS will announce to MA organizations and other interested parties the MA region-specific non-drug monthly benchmark amount for the year involved for each MA region and each MA regional plan for which a bid was submitted under § 422.256.

(b) *Advance notice of changes in methodology.* (1) No later than 45 days before

making the announcement under paragraph (a)(1) of this section, CMS notifies MA organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.

(2) The MA organizations have 15 days to comment on the proposed changes.

§ 422.314 Special rules for beneficiaries enrolled in MA MSA plans.

(a) *Establishment and designation of medical savings account (MSA).* A beneficiary who elects coverage under an MA MSA plan—

(1) Must establish an MA MSA with a trustee that meets the requirements of paragraph (b) of this section; and

(2) If he or she has more than one MA MSA, designate the particular account to which payments under the MA MSA plan are to be made.

(b) *Requirements for MSA trustees.* An entity that acts as a trustee for an MA MSA must—

(1) Register with CMS;

(2) Certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the Internal Revenue Code of 1986, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the MA MSA provisions of section 138 of the Internal Revenue Code of 1986; and

(4) Provide any other information that CMS may require.

(c) *Deposit in the MA MSA.* (1) The payment is calculated as follows:

(i) The monthly MA MSA premium is compared with 1/12 of the annual capitation rate applied under this section for the.

(ii) If the monthly MA MSA premium is less than 1/12 of the annual capitation rate applied under this section for the area, the difference is the amount to be deposited in the MA MSA for each month for which the beneficiary is enrolled in the MSA plan.

(2) CMS deposits the full amount to which a beneficiary is entitled under paragraph (c)(1)(ii) of this section for the calendar year, beginning with the month in which MA MSA coverage begins.

(3) If the beneficiary's coverage under the MA MSA plan ends before the end of the calendar year, CMS recovers the amount that corresponds to the remaining months of that year.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.316 Special rules for payments to Federally qualified health centers.

If an enrollee in an MA plan receives a service from a Federally qualified health center (FQHC) that has a written agreement with the MA organization offering the plan concerning the provision of this service (including the agreement required under section 1857(e)(3) of the Act and as codified in § 422.527)—

(a) CMS will pay the amount determined under section 1833(a)(3)(B) of the Act directly to the FQHC at a minimum on a quarterly basis, less the amount the FQHC would receive for the MA enrollee from the MA organization and taking into account the cost sharing amount paid by the enrollee; and

(b) CMS will not reduce the amount of the monthly payments under this section as a result of the application of paragraph (a) of this section.

EFFECTIVE DATE NOTE: At 70 FR 52027, Sept. 1, 2005, § 422.316 was suspended, effective September 1, 2005 through January 1, 2006.

§ 422.318 Special rules for coverage that begins or ends during an inpatient hospital stay.

(a) *Applicability.* This section applies to inpatient services in a ''subsection (d) hospital'' as defined in section 1886(d)(1)(B) of the Act, a psychiatric hospital described in section 1886(d)(1)(B)(i) of the act, a rehabilitation hospital described in section 1886(d)(1)(B)(ii) of the Act, a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B) of the Act, or a long-term care hospital (described in section 1886(d)(1)(B)(iv)).

(b) *Coverage that begins during an inpatient stay.* If coverage under an MA plan offered by an MA organization begins while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) Payment for inpatient services until the date of the beneficiary's discharge is made by the previous MA organization or original Medicare, as appropriate;

(2) The MA organization offering the newly-elected MA plan is not responsible for the inpatient services until the date after the beneficiary's discharge; and

(3) The MA organization offering the newly-elected MA plan is paid the full amount otherwise payable under this subpart.

(c) *Coverage that ends during an inpatient stay*. If coverage under an MA plan offered by an MA organization ends while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) The MA organization is responsible for the inpatient services until the date of the beneficiary's discharge;

(2) Payment for those services during the remainder of the stay is not made by original Medicare or by any succeeding MA organization offering a newly-elected MA plan; and

(3) The MA organization that no longer provides coverage receives no payment for the beneficiary for the period after coverage ends.

§ 422.320 Special rules for hospice care.

(a) *Information*. An MA organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the MA organization or a related entity) if—

(1) A Medicare hospice program is located within the plan's service area; or

(2) It is common practice to refer patients to hospice programs outside that area.

(b) *Enrollment status*. Unless the enrollee disenrolls from the MA plan, a beneficiary electing hospice continues his or her enrollment in the MA plan and is entitled to receive, through the MA plan, any benefits other than those that are the responsibility of the Medicare hospice.

(c) *Payment*. (1) No payment is made to an MA organization on behalf of a Medicare enrollee who has elected hospice care under § 418.24 of this chapter, except for the portion of the payment attributable to the beneficiary rebate for the MA plan, described in § 422.266(b)(1) plus the amount of the monthly prescription drug payment described in § 423.315 (if any). This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the election is terminated.

(2) During the time the hospice election is in effect, CMS' monthly capitation payment to the MA organization is reduced to the sum of—

(i) An amount equal to the beneficiary rebate for the MA plan, as described in § 422.304(a)(3) or to zero for plans with no beneficiary rebate, described at § 422.304(a)(2); and

(ii) The amount of the monthly prescription drug payment described in § 423.315 (if any).

(3) In addition, CMS pays through the original Medicare program (subject to the usual rules of payment)—

(i) The hospice program for hospice care furnished to the Medicare enrollee; and

(ii) The MA organization, provider, or supplier for other Medicare-covered services to the enrollee.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.322 Source of payment and effect of MA plan election on payment.

(a) *Source of payments*. (1) Payments under this subpart for original fee-for-service benefits to MA organizations or MA MSAs are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. CMS determines the proportions to reflect the relative weight that benefits under Part A, and benefits under Part B represents of the actuarial value of the total benefits under title XVIII of the Act.

(2) Payments to MA-PD organizations for statutory drug benefits provided under this title are made from

the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

(b) *Payments to the MA organization.* Subject to § 412.105(g) and § 413.86(d) of this chapter and § 422.109, § 422.316, and § 422.320, CMS' payments under a contract with an MA organization (described in § 422.304) with respect to an individual electing an MA plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

(c) *Only the MA organization entitled to payment.* Subject to § 422.314, § 422.316, § 422.318, § 422.320, and § 422.520 and sections 1886(d)(11) and 1886(h)(3)(D) of the Act, only the MA organization is entitled to receive payment from CMS under title XVIII of the Act for items and services furnished to the individual.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.324 Payments to MA organizations for graduate medical education costs.

(a) MA organizations may receive direct graduate medical education payments for the time that residents spend in non-hospital provider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs.

(b) MA organizations may receive direct graduate medical education payments if all of the following conditions are met:

(1) The resident spends his or her time assigned to patient care activities.

(2) The MA organization incurs ''all or substantially all'' of the costs for the training program in the non-hospital setting as defined in § 413.86(b) of this chapter.

(3) There is a written agreement between the MA organization and the non-hospital site that indicates the MA organization will incur the costs of the resident's salary and fringe benefits and provide reasonable compensation to the non-hospital site for teaching activities.

(c) An MA organization's allowable direct graduate medical education costs, subject to the redistribution and community support principles specified in § 413.85(c) of this chapter, consist of—

(1) Residents' salaries and fringe benefits (including travel and lodging where applicable); and

(2) Reasonable compensation to the non-hospital site for teaching activities related to the training of medical residents.

(d) The direct graduate medical education payment is equal to the product of—

(1) The lower of—

(i) The MA organization's allowable costs per resident as defined in paragraph (c) of this section; or

(ii) The national average per resident amount; and

(2) Medicare's share, which is equal to the ratio of the number of Medicare beneficiaries enrolled to the total number of individuals enrolled in the MA organization.

(e) Direct graduate medical education payments made to MA organizations under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

Subpart H—Provider-Sponsored Organizations

EDITORIAL NOTE: Nomenclature changes to subpart H appear at 63 FR 35098, 35099, June 26, 1998.

§ 422.350 Basis, scope, and definitions.

(a) *Basis and scope.* This subpart is based on sections 1851 and 1855 of the Act which, in part,—

(1) Authorize provider sponsored organizations, (PSOs), to contract as a MA plan;

(2) Require that a PSO meet certain qualifying requirements; and

(3) Provide for waiver of State licensure for PSOs under specified conditions.

(b) *Definitions.* As used in this subpart (unless otherwise specified)—

Capitation payment means a fixed per enrollee per month amount paid for contracted services without regard to the type, cost, or frequency of services furnished.

Cash equivalent means those assets excluding accounts receivable that can

be exchanged on an equivalent basis as cash, or converted into cash within 90 days from their presentation for exchange.

Control means that an individual, group of individuals, or entity has the power, directly or indirectly, to direct or influence significantly the actions or policies of an organization or institution.

Current ratio means total current assets divided by total current liabilities.

Deferred acquisition costs are those costs incurred in starting or purchasing a business. These costs are capitalized as intangible assets and carried on the balance sheet as deferred charges since they benefit the business for periods after the period in which the costs were incurred.

Engaged in the delivery of health care services means—

(1) For an individual, that the individual directly furnishes health care services, or

(2) For an entity, that the entity is organized and operated primarily for the purpose of furnishing health care services directly or through its provider members or entities.

Generally accepted accounting principles (GAAP) means broad rules adopted by the accounting profession as guides in measuring, recording, and reporting the financial affairs and activities of a business to its owners, creditors and other interested parties.

Guarantor means an entity that—

(1) Has been approved by CMS as meeting the requirements to be a guarantor; and

(2) Obligates its resources to a PSO to enable the PSO to meet the solvency requirements required to contract with CMS as an MA organization.

Health care delivery assets (HCDAs) means any tangible assets that are part of a PSO's operation, including hospitals and other medical facilities and their ancillary equipment, and such property as may be reasonably required for the PSO's principal office or for such other purposes as the PSO may need for transacting its business.

Insolvency means a condition in which the liabilities of the debtor exceed the fair valuation of its assets.

Net worth means the excess of total assets over total liabilities, excluding fully subordinated debt or subordinated liabilities.

Provider-sponsored organization (PSO) means a public or private entity that—

(1) Is established or organized, and operated, by a provider or group of affiliated providers;

(2) Provides a substantial proportion (as defined in §422.352) of the health care services under the MA contract directly through the provider or affiliated group of providers; and

(3) When it is a group, is composed of affiliated providers who—

(i) Share, directly or indirectly, substantial financial risk, as determined under §422.356, for the provision of services that are the obligation of the PSO under the MA contract; and

(ii) Have at least a majority financial interest in the PSO.

Qualified actuary means a member in good standing of the American Academy of Actuaries or a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial determination and is satisfactory to CMS.

Statutory accounting practices means those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State that PSO operates.

Subordinated debt means an obligation that is owed by an organization, that the creditor of the obligation, by law, agreement, or otherwise, has a lower repayment rank in the hierarchy of creditors than another creditor. The creditor would be entitled to repayment only after all higher ranking creditors' claims have been satisfied. A debt is fully subordinated if it has a lower repayment rank than all other classes of creditors.

Subordinated liability means claims liabilities otherwise due to providers that are retained by the PSO to meet net worth requirements and are fully subordinated to all other creditors.

Uncovered expenditures means those expenditures for health care services that are the obligation of an organization, for which an enrollee may also be liable in the event of the organization's insolvency and for which no alternative arrangements have been made

that are acceptable to CMS. They include expenditures for health care services for which the organization is at risk, such as out-of-area services, referral services and hospital services. However, they do not include expenditures for services when a provider has agreed not to bill the enrollee.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 25376, May 7, 1998; 63 FR 35098, June 26, 1998]

§ 422.352 Basic requirements.

(a) *General rule.* An organization is considered a PSO for purposes of a MA contract if the organization—

(1) Has obtained a waiver of State licensure as provided for under § 422.370;

(2) Meets the definition of a PSO set forth in § 422.350 and other applicable requirements of this subpart; and

(3) Is effectively controlled by the provider or, in the case of a group, by one or more of the affiliated providers that established and operate the PSO.

(b) *Provision of services.* A PSO must demonstrate to CMS's satisfaction that it is capable of delivering to Medicare enrollees the range of services required under a contract with CMS. Each PSO must deliver a substantial proportion of those services directly through the provider or the affiliated providers responsible for operating the PSO. Substantial proportion means—

(1) For a non-rural PSO, not less than 70% of Medicare services covered under the contract.

(2) For a rural PSO, not less than 60% of Medicare services covered under the contract.

(c) *Rural PSO.* To qualify as a rural PSO, a PSO must—

(1) Demonstrate to CMS that—

(i) It has available in the rural area, as defined in § 412.62(f) of this chapter, routine services including but not limited to primary care, routine specialty care, and emergency services; and

(ii) The level of use of providers outside the rural area is consistent with general referral patterns for the area; and

(2) Enroll Medicare beneficiaries, the majority of which reside in the rural area the PSO serves.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998; 65 FR 40327, June 29, 2000]

§ 422.354 Requirements for affiliated providers.

A PSO that consists of two or more providers must demonstrate to CMS'S satisfaction that it meets the following requirements:

(a) The providers are affiliated. For purposes of this subpart, providers are affiliated if, through contract, ownership, or otherwise—

(1) One provider, directly or indirectly, controls, is controlled by, or is under common control with another;

(2) Each provider is part of a lawful combination under which each shares substantial financial risk in connection with the PSO's operations;

(3) Both, or all, providers are part of a controlled group of corporations under section 1563 of the Internal Revenue Code of 1986; or

(4) Both, or all, providers are part of an affiliated service group under section 414 of that Code.

(b) Each affiliated provider of the PSO shares, directly or indirectly, substantial financial risk for the furnishing of services the PSO is obligated to provide under the contract.

(c) Affiliated providers, as a whole or in part, have at least a majority financial interest in the PSO.

(d) For purposes of paragraph(a)(1) of this section, control is presumed to exist if one party, directly or indirectly, owns, controls, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance right of another.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.356 Determining substantial financial risk and majority financial interest.

(a) *Determining substantial financial risk.* The PSO must demonstrate to CMS's satisfaction that it apportions a significant part of the financial risk of the PSO enterprise under the MA contract to each affiliated provider. The PSO must demonstrate that the financial arrangements among its affiliated providers constitute ''substantial'' risk in the PSO for each affiliated provider. The following mechanisms may constitute risk-sharing arrangements, and may have to be used in combination to

demonstrate substantial financial risk in the PSO enterprise.

(1) Agreement by a provider to accept capitation payment for each Medicare enrollee.

(2) Agreement by a provider to accept as payment a predetermined percentage of the PSO premium or the PSO's revenue.

(3) The PSO's use of significant financial incentives for its affiliated providers, with the aim of achieving utilization management and cost containment goals. Permissible methods include the following:

(i) Affiliated providers agree to a withholding of a significant amount of the compensation due them, to be used for any of the following:

(A) To cover losses of the PSO.

(B) To cover losses of other affiliated providers.

(C) To be returned to the affiliated provider if the PSO meets its utilization management or cost containment goals for the specified time period.

(D) To be distributed among affiliated providers if the PSO meets its utilization management or cost-containment goals for the specified time period.

(ii) Affiliated providers agree to preestablished cost or utilization targets for the PSO and to subsequent significant financial rewards and penalties (which may include a reduction in payments to the provider) based on the PSO's performance in meeting the targets.

(4) Other mechanisms that demonstrate significant shared financial risk.

(b) *Determining majority financial interest*. Majority financial interest means maintaining effective control of the PSO.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.370 Waiver of State licensure.

For an organization that seeks to contract to offer an MA plan under this subpart, CMS may waive the State licensure requirement of section 1855(a)(1) of the Act if—

(a) The organization requests a waiver no later than November 1, 2002; and

(b) CMS determines there is a basis for a waiver under § 422.372.

[63 FR 25376, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.372 Basis for waiver of State licensure.

(a) *General rule*. Subject to this section and to paragraphs (a) and (e) of § 422.374, CMS may waive the State licensure requirement if the organization has applied (except as provided in paragraph (b)(4) of this section) for the most closely appropriate State license or authority to conduct business as an MA plan.

(b) *Basis for waiver of State licensure*. Any of the following may constitute a basis for CMS's waiver of State licensure.

(1) *Failure to act timely on application*. The State failed to complete action on the licensing application within 90 days of the date the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment*. The State has—

(i) Denied the license application on the basis of material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) Required, as a condition of licensure that the organization offer any product or plan other than an MA plan.

(3) *Denial of application based on different solvency requirements*. (i) The State has denied the application, in whole or in part, on the basis of the organization's failure to meet solvency requirements that are different from those set forth in §§ 422.380 through 422.390; or

(ii) CMS determines that the State has imposed, as a condition of licensure, any documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, or standards set forth by CMS to implement, monitor, and enforce §§ 422.380 through 422.390.

(4) *State declines to accept licensure application.* The appropriate State licensing authority has given the organization written notice that it will not accept its licensure application.

[63 FR 35098, June 26, 1998]

§ 422.374 Waiver request and approval process.

(a) *Substantially complete waiver request.* The organization must submit a substantially complete waiver request that clearly demonstrates and documents its eligibility for a waiver under § 422.372.

(b) CMS gives the organization written notice of granting or denial of waiver within 60 days of receipt of a substantially complete waiver request.

(c) *Subsequent waiver requests.* An organization that has had a waiver request denied, may submit subsequent waiver requests until November 1, 2002.

(d) *Effective date.* A waiver granted under § 422.370 will be effective on the effective date of the organization's MA contract.

(e) *Consistency in application.* CMS reserves the right to revoke waiver eligibility if it subsequently determines that the organization's MA application is significantly different from the application submitted by the organization to the State licensing authority.

[63 FR 25377, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.376 Conditions of the waiver.

A waiver granted under this section is subject to the following conditions:

(a) *Limitation to State.* The waiver is effective only for the particular State for which it is granted and does not apply to any other State. For each State in which the organization wishes to operate without a State license, it must submit a waiver request and receive a waiver.

(b) *Limitation to 36-month period.* The waiver is effective for 36 months or through the end of the calendar year in which the 36 month period ends unless it is revoked based on paragraph (c) of this section.

(c) *Mid-period revocation.* During the waiver period (set forth in paragraph (b) of this section), the waiver is automatically revoked upon—

(1) Termination of the MA contract;

(2) The organization's compliance with the State licensure requirement of section 1855(a)(1) of the Act; or

(3) The organization's failure to comply with § 422.378.

[63 FR 25377, May 7, 1998]

§ 422.378 Relationship to State law.

(a) *Preemption of State law.* Any provisions of State law that relate to the licensing of the organization and that prohibit the organization from providing coverage under a contract as specified in this subpart, are superseded.

(b) *Consumer protection and quality standards.* (1) A waiver of State licensure granted under this subpart is conditioned upon the organization's compliance with all State consumer protection and quality standards that—

(i) Would apply to the organization if it were licensed under State law;

(ii) Generally apply to other MA organizations and plans in the State; and

(iii) Are consistent with the standards established under this part.

(2) The standards specified in paragraph (b)(1) of this section do not include any standard preempted under section 1856(b)(3)(B) of the Act.

(c) *Incorporation into contract.* In contracting with an organization that has a waiver of State licensure, CMS incorporates into the contract the requirements specified in paragraph (b) of this section.

(d) *Enforcement.* CMS may enter into an agreement with a State for the State to monitor and enforce compliance with the requirements specified in paragraph (b) of this section by an organization that has obtained a waiver under this subpart.

[63 FR 25377, May 7, 1998]

§ 422.380 Solvency standards.

General rule. A PSO or the legal entity of which the PSO is a component that has been granted a waiver under § 422.370 must have a fiscally sound operation that meets the requirements of §§ 422.382 through 422.390.

[63 FR 25377, May 7, 1998]

§ 422.382 Minimum net worth amount.

(a) At the time an organization applies to contract with CMS as a PSO under this part, the organization must have a minimum net worth amount, as determined under paragraph (c) of this section, of:

(1) At least $1,500,000, except as provided in paragraph (a)(2) of this section.

(2) No less than $1,000,000 based on evidence from the organization's financial plan (under § 422.384) demonstrating to CMS's satisfaction that the organization has available to it an administrative infrastructure that CMS considers appropriate to reduce, control or eliminate start-up administrative costs.

(b) After the effective date of a PSO's MA contract, a PSO must maintain a minimum net worth amount equal to the greater of—

(1) One million dollars;

(2) Two percent of annual premium revenues as reported on the most recent annual financial statement filed with CMS for up to and including the first $150,000,000 of annual premiums and 1 percent of annual premium revenues on premiums in excess of $150,000,000;

(3) An amount equal to the sum of three months of uncovered health care expenditures as reported on the most recent financial statement filed with CMS; or

(4) Using the most recent financial statement filed with CMS, an amount equal to the sum of—

(i) Eight percent of annual health care expenditures paid on a non-capitated basis to non-affiliated providers; and

(ii) Four percent of annual health care expenditures paid on a capitated basis to non-affiliated providers plus annual health care expenditures paid on a non-capitated basis to affiliated providers.

(iii) Annual health care expenditures that are paid on a capitated basis to affiliated providers are not included in the calculation of the net worth requirement (regardless of downstream arrangements from the affiliated provider) under paragraphs (a) and (b)(4) of this section.

(c) *Calculation of the minimum net worth amount*—(1) *Cash requirement.* (i) At the time of application, the organization must maintain at least $750,000 of the minimum net worth amount in cash or cash equivalents.

(ii) After the effective date of a PSO's MA contract, a PSO must maintain the greater of $750,000 or 40 percent of the minimum net worth amount in cash or cash equivalents.

(2) *Intangible assets.* An organization may include intangible assets, the value of which is based on Generally Accepted Accounting Principles (GAAP), in the minimum net worth amount calculation subject to the following limitations—

(i) *At the time of application.* (A) Up to 20 percent of the minimum net worth amount, provided at least $1,000,000 of the minimum net worth amount is met through cash or cash equivalents; or

(B) Up to 10 percent of the minimum net worth amount, if less than $1,000,000 of the minimum net worth amount is met through cash or cash equivalents, or if CMS has used its discretion under paragraph (a)(2) of this section.

(ii) *From the effective date of the contract.* (A) Up to 20 percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is met by cash or cash equivalents; or

(B) Up to ten percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is not met by cash or cash equivalents.

(3) *Health care delivery assets.* Subject to the other provisions of this section, a PSO may apply 100 percent of the GAAP depreciated value of health care delivery assets (HCDAs) to satisfy the minimum net worth amount.

(4) *Other assets.* A PSO may apply other assets not used in the delivery of health care provided that those assets are valued according to statutory accounting practices (SAP) as defined by the State.

(5) *Subordinated debts and subordinated liabilities.* Fully subordinated debt and subordinated liabilities are excluded from the minimum net worth amount calculation.

(6) *Deferred acquisition costs.* Deferred acquisition costs are excluded from the calculation of the minimum net worth amount.

[63 FR 25377, May 7, 1998, as amended at 64 FR 71678, Dec. 22, 1999]

§ 422.384 Financial plan requirement.

(a) *General rule.* At the time of application, an organization must submit a financial plan acceptable to CMS.

(b) *Content of plan.* A financial plan must include—

(1) A detailed marketing plan;

(2) Statements of revenue and expense on an accrual basis;

(3) Cash-flow statements;

(4) Balance sheets;

(5) Detailed justifications and assumptions in support of the financial plan including, where appropriate, certification of reserves and actuarial liabilities by a qualified actuary; and

(6) If applicable, statements of the availability of financial resources to meet projected losses.

(c) *Period covered by the plan.* A financial plan must—

(1) Cover the first 12 months after the estimated effective date of a PSO's MA contract; or

(2) If the PSO is projecting losses, cover 12 months beyond the end of the period for which losses are projected.

(d) *Funding for projected losses.* Except for the use of guarantees, LOC, and other means as provided in § 422.384(e), (f) and (g), an organization must have the resources for meeting projected losses on its balance sheet in cash or a form that is convertible to cash in a timely manner, in accordance with the PSO's financial plan.

(e) *Guarantees and projected losses.* Guarantees will be an acceptable resource to fund projected losses, provided that a PSO—

(1) Meets CMS's requirements for guarantors and guarantee documents as specified in § 422.390; and

(2) Obtains from the guarantor cash or cash equivalents to fund the projected losses timely, as follows—

(i) Prior to the effective date of a PSO's MA contract, the amount of the projected losses for the first two quarters;

(ii) During the first quarter and prior to the beginning of the second quarter of a PSO's MA contract, the amount of projected losses through the end of the third quarter; and

(iii) During the second quarter and prior to the beginning of the third quarter of a PSO's MA contract, the amount of projected losses through the end of the fourth quarter.

(3) If the guarantor complies with the requirements in paragraph (e)(2) of this section, the PSO, in the third quarter, may notify CMS of its intent to reduce the period of advance funding of projected losses. CMS will notify the PSO within 60 days of receiving the PSO's request if the requested reduction in the period of advance funding will not be accepted.

(4) If the guarantee requirements in paragraph (e)(2) of this section are not met, CMS may take appropriate action, such as requiring funding of projected losses through means other than a guarantee. CMS retains discretion to require other methods or timing of funding, considering factors such as the financial condition of the guarantor and the accuracy of the financial plan.

(f) *Letters of credit.* Letters of credit are an acceptable resource to fund projected losses, provided they are irrevocable, unconditional, and satisfactory to CMS. They must be capable of being promptly paid upon presentation of a sight draft under the letters of credt without further reference to any other agreement, document, or entity.

(g) *Other means.* If satisfactory to CMS, and for periods beginning one year after the effective date of a PSO's MA contract, a PSO may use the following to fund projected losses—

(1) Lines of credit from regulated financial institutions;

(2) Legally binding agreements for capital contributions; or

(3) Legally binding agreements of a similar quality and reliability as permitted in paragraphs (g)(1) and (2) of this section.

(h) *Application of guarantees, Letters of credit or other means of funding projected losses.* Notwithstanding any other provision of this section, a PSO may use guarantees, letters of credit and, beginning one year after the effective date of a PSO's MA contract, other means of funding projected losses, but only in a

combination or sequence that CMS considers appropriate.

[63 FR 25378, May 7, 1998, as amended at 63 FR 35098, June 26, 1998; 64 FR 71678, Dec. 22, 1999]

§ 422.386 Liquidity.

(a) A PSO must have sufficient cash flow to meet its financial obligations as they become due and payable.

(b) To determine whether the PSO meets the requirement in paragraph (a) of this section, CMS will examine the following—

(1) The PSO's timeliness in meeting current obligations;

(2) The extent to which the PSO's current ratio of assets to liabilities is maintained at 1:1 including whether there is a declining trend in the current ratio over time; and

(3) The availability of outside financial resources to the PSO.

(c) If CMS determines that a PSO fails to meet the requirement in paragraph (b)(1) of this section, CMS will require the PSO to initiate corrective action and pay all overdue obligations.

(d) If CMS determines that a PSO fails to meet the requirement of paragraph (b)(2) of this section, CMS may require the PSO to initiate corrective action to—

(1) Change the distribution of its assets;

(2) Reduce its liabilities; or

(3) Make alternative arrangements to secure additional funding to restore the PSO's current ratio to 1:1.

(e) If CMS determines that there has been a change in the availability of outside financial resources as required by paragraph (b)(3) of this section, CMS requires the PSO to obtain funding from alternative financial resources.

[63 FR 25378, May 7, 1998, as amended at 64 FR 71678, Dec. 22, 1999]

§ 422.388 Deposits.

(a) *Insolvency deposit.* (1) At the time of application, an organization must deposit $100,000 in cash or securities (or any combination thereof) into an account in a manner that is acceptable to CMS.

(2) The deposit must be restricted to use in the event of insolvency to help assure continuation of services or pay costs associated with receivership or liquidation.

(3) At the time of the PSO's application for an MA contract and, thereafter, upon CMS's request, a PSO must provide CMS with proof of the insolvency deposit, such proof to be in a form that CMS considers appropriate.

(b) *Uncovered expenditures deposit.* (1) If at any time uncovered expenditures exceed 10 percent of a PSO's total health care expenditures, then the PSO must place an uncovered expenditures deposit into an account with any organization or trustee that is acceptable to CMS.

(2) The deposit must at all times have a fair market value of an amount that is 120 percent of the PSO's outstanding liability for uncovered expenditures for enrollees, including incurred, but not reported claims.

(3) The deposit must be calculated as of the first day of each month required and maintained for the remainder of each month required.

(4) If a PSO is not otherwise required to file a quarterly report, it must file a report within 45 days of the end of the calendar quarter with information sufficient to demonstrate compliance with this section.

(5) The deposit required under this section is restricted and in trust for CMS's use to protect the interests of the PSO's Medicare enrollees and to pay the costs associated with administering the insolvency. It may be used only as provided under this section.

(c) A PSO may use the deposits required under paragraphs (a) and (b) of this section to satisfy the PSO's minimum net worth amount required under § 422.382(a) and (b).

(d) All income from the deposits or trust accounts required under paragraphs (a) and (b) of this section, are considered assets of the PSO. Upon CMS's approval, the income from the deposits may be withdrawn.

(e) On prior written approval from CMS, a PSO that has made a deposit under paragraphs (a) or (b) of this section, may withdraw that deposit or any part thereof if—

(1) A substitute deposit of cash or securities of equal amount and value is made;

(2) The fair market value exceeds the amount of the required deposit; or

(3) The required deposit under paragraphs (a) or (b) of this section is reduced or eliminated.

[63 FR 25379, May 7, 1998]

§ 422.390 Guarantees.

(a) *General policy*. A PSO, or the legal entity of which the PSO is a component, may apply to CMS to use the financial resources of a guarantor for the purpose of meeting the requirements in § 422.384. CMS has the discretion to approve or deny approval of the use of a guarantor.

(b) *Request to use a guarantor*. To apply to use the financial resources of a guarantor, a PSO must submit to CMS—

(1) Documentation that the guarantor meets the requirements for a guarantor under paragraph (c) of this section; and

(2) The guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the guarantor's balance sheets, profit and loss statements, and cash flow statements.

(c) *Requirements for guarantor*. To serve as a guarantor, an organization must meet the following requirements:

(1) Be a legal entity authorized to conduct business within a State of the United States.

(2) Not be under Federal or State bankruptcy or rehabilitation proceedings.

(3) Have a net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PSO guarantee.

(4) If the guarantor is regulated by a State insurance commissioner, or other State official with authority for risk-bearing entities, it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.

(5) If the guarantor is not regulated by a State insurance commissioner, or other similar State official it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets.

(d) *Guarantee document*. If the guarantee request is approved, a PSO must submit to CMS a written guarantee document signed by an appropriate authority of the guarantor. The guarantee document must—

(1) State the financial obligation covered by the guarantee;

(2) Agree to—

(i) Unconditionally fulfill the financial obligation covered by the guarantee; and

(ii) Not subordinate the guarantee to any other claim on the resources of the guarantor;

(3) Declare that the guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and

(4) Meet other conditions as CMS may establish from time to time.

(e) *Reporting requirement*. A PSO must submit to CMS the current internal financial statements and annual audited financial statements of the guarantor according to the schedule, manner, and form that CMS requests.

(f) *Modification, substitution, and termination of a guarantee*. A PSO cannot modify, substitute or terminate a guarantee unless the PSO—

(1) Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;

(2) Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the PSO; and

(3) Demonstrates how the PSO will meet the requirements of this section.

(g) *Nullification*. If at any time the guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the PSO that it ceases to recognize the guarantee document. In the event of this nullification, a PSO must—

(1) Meet the applicable requirements of this section within 15 business days; and

(2) If required by CMS, meet a portion of the applicable requirements in

less than the time period granted in paragraph (g)(1) of this section.

[63 FR 25379, May 7, 1998]

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§ 422.400 State licensure requirement.

Except in the case of a PSO granted a waiver under subpart H of this part, each MA organization must—

(a) Be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more MA plans;

(b) If not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an MA organization; and

(c) Demonstrate to CMS that—

(1) The scope of its license or authority allows the organization to offer the type of MA plan or plans that it intends to offer in the State; and

(2) If applicable, it has obtained the State certification required under paragraph (b) of this section.

§ 422.402 Federal preemption of State law.

The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to the MA plans that are offered by MA organizations.

[70 FR 4733, Jan. 28, 2005]

§ 422.404 State premium taxes prohibited.

(a) *Basic rule*. No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA enrollees under subpart G of this part, or with respect to any payment made to MA plans by beneficiaries, or payment to MA plans by a third party on a beneficiary's behalf.

(b) *Construction*. Nothing in this section shall be construed to exempt any MA organization from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

[63 FR 35099, June 26, 1998, as amended at 70 FR 4733, Jan. 28, 2005]

Subpart J—Special Rules for MA Regional Plans

SOURCE: 70 FR 4733, Jan. 28, 2005, unless otherwise noted.

§ 422.451 Moratorium on new local preferred provider organization plans.

CMS will not approve the offering of a local preferred provider organization plan during 2006 or 2007 in a service area unless the MA organization seeking to offer the plan was offering a local preferred provider organization plan in the service area before December 31, 2005.

§ 422.455 Special rules for MA Regional Plans.

(a) *Coverage of entire MA region*. The service area for an MA regional plan will consist of an entire MA region established under paragraph (b) of this section, and an MA region may not be segmented as described in § 422.262(c)(2).

(b) *Establishment of MA regions*—(1) *MA region*. The term ''MA region'' means a region within the 50 States and the District of Columbia as established by CMS under this section.

(2) *Establishment*—(i) *Initial establishment*. By January 1, 2005, CMS will establish and publish the MA regions.

(ii) *Periodic review and revision of service areas*. CMS may periodically review MA regions and may revise the regions if it determines the revision to be appropriate.

(3) *Requirements for MA regions.* CMS will establish, and may revise, MA regions in a manner consistent with the following:

(i) *Number of regions.* There will be no fewer than 10 regions, and no more than 50 regions.

(ii) *Maximizing availability of plans.* The main purpose of the regions is to maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, or geographic location, especially those residing in rural areas.

(4) *Market survey and analysis.* Before establishing MA regions, CMS will conduct a market survey and analysis, including an examination of current insurance markets, to assist CMS in determining how the regions should be established.

(c) *National plan.* An MA regional plan can be offered in more than one MA region (including all regions).

§ 422.458 Risk sharing with regional MA organizations for 2006 and 2007.

(a) *Terminology.* For purposes of this section—

Allowable costs means, with respect to an MA regional plan offered by an organization for a year, the total amount of costs that the organization incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan in the region in the year and in providing rebatable integrated benefits, as defined in this paragraph, reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.

Rebatable integrated benefits means those non-drug supplemental benefits that are funded through beneficiary rebates (described at § 422.266(b)(1)) and that CMS determines are additional health benefits not covered under the original Medicare program option and that require expenditures by the plan. For purposes of the calculation of risk corridors, these are the only supplemental benefits that count toward allowable costs.

Target amount means, with respect to an MA regional plan offered by an organization in a year, the total amount of payments made to the organization for enrollees in the plan for the year (which includes payments attributable to benefits under the original Medicare fee-for-service program option as defined in § 422.100(c)(1), the total of the MA monthly basic beneficiary premium collectable for those enrollees for the year, and the total amount of rebatable integrated benefits), reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare fee-for-service program option or to rebatable integrated benefits.

(b) *Application of risk corridors for benefits covered under original fee-for-service Medicare*—(1) *General rule.* This section will only apply to MA regional plans offered during 2006 or 2007.

(2) *Notification of allowable costs under the plan.* In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization must notify CMS, before that date in the succeeding year as CMS specifies, of—

(i) Its total amount of costs that the organization

incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan (as described in paragraph (a) of this section).

(ii) Its total amount of costs that the organization incurred in providing rebatable integrated benefits for all enrollees under the plan (as described in paragraph (a) of this section), and, with respect to those benefits, the portion of those costs that is attributable to administrative expenses that is in addition to the administrative expense incurred in provision of benefits under the original Medicare fee-for-service program option.

(c) *Adjustment of payment*—(1) *No adjustment if allowable costs within 3 percent of target amount.* If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there will be no payment adjustment under this section for the plan and year.

(2) *Increase in payment if allowable costs above 103 percent of target amount*—(i) *Costs between 103 and 108 percent of target amount.* If the allowable costs for the plan for the year are greater than

103 percent, but not greater than 108 percent, of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount equal to 50 percent of the difference between those allowable costs and 103 percent of that target amount.

(ii) *Costs above 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) of the Act by an amount equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between those allowable costs and 108 percent of that target amount.

(3) *Reduction in payment if allowable costs below 97 percent of target amount*—(i) *Costs between 92 and 97 percent of target amount.* If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and those allowable costs.

(ii) *Costs below 92 percent of target amount.* If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a)of the Act) by an amount (or otherwise recover from the plan an amount) equal to the sum of-

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between 92 percent of that target amount and those allowable costs.

(d) *Disclosure of information*—(1) *General rule.* Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section; and

(2) According to § 422.504(d)(1)(iii), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

(3) *Restriction on use of information.* Information disclosed or obtained for the purposes of this section may be used by officers, employees, and contractors of DHHS only for the purposes of, and to the extent necessary in, implementing this section.

(e) *Organizational and financial requirements*—(1) *General rule.* Regional MA plans offered by MA organizations must be licensed under State law, or otherwise authorized under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more plans. However, as provided for under this section, MA organizations offering MA regional plans may obtain a temporary waiver of State licensure. In the case of an MA organization that is offering an MA regional plan in an MA region, and is not licensed in each State in which it offers such an MA regional plan, the following rules apply:

(i) The MA organization must be licensed to bear risk in at least one State of the region.

(ii) For the other States in a region in which the organization is not licensed to bear risk, if it demonstrates to CMS that it has filed the necessary application to meet those requirements, CMS may temporarily waive the licensing requirement with respect to each State for a period of time as CMS determines appropriate for the timely processing of the application by the State or States.

(iii) If the State licensing application or applications are denied, CMS may extend the licensing waiver through the end of the plan year or as CMS determines appropriate to provide for a transition.

(2) *Selection of appropriate State.* In the case of an MA organization to which CMS grants a waiver and that is

licensed in more than one State in a region, the MA organization will select one of the States, the rules of which shall apply in States where the organization is not licensed for the period of the waiver.

(f) *Regional stabilization fund*—(1) *Establishment*. The MA Regional Plan Stabilization Fund (referred to in this paragraph (f) as the ''Fund'') is available beginning in 2007 for two purposes:

(i) *Plan entry*. To provide incentives to have MA regional plans offered in each MA region under paragraph (f)(4) of this section.

(ii) *Plan retention*. To provide incentives to retain MA regional plans in certain MA regions with below-national-average MA market penetration under paragraph (f)(5) of this section.

(2) *Availability of funding from savings*. Funds made available under section 1853(f) of the Act are transferred into a special account in the Treasury from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) of the Act, ''payments From Trust Funds,'' on a monthly basis.

(3) *Funding limitation*—(i) *General rule*. The total amount expended from the Fund as a result of the application of this section through the end of a calendar year may not exceed the amount available to the Fund as of the first day of that year. For purposes of this section, amounts that are expended under this title insofar as those amounts would not have been expended but for the application of this section will be counted as amounts expended as a result of that application.

(ii) *Application of limitation*. CMS will obligate funds from the Fund for a year only if the Chief Actuary of CMS and the appropriate budget officer certify that there are available in the Fund at the beginning of the year sufficient amounts to cover all of those obligations incurred during the year consistent with paragraph (f)(3)(i) of this section. CMS will take those steps, in connection with computing additional payment amounts under paragraphs (f)(4) and (f)(5) of this section and including limitations on enrollment in MA regional plans receiving those payments or computing lower payment amounts, to ensure that sufficient funds are available to make those payments for the entire year.

(4) *Plan entry funding*—(i) *General rule*. Funding is available under this paragraph for a year in the following situations:

(A) *National plan*. For a national bonus payment described in paragraph (f)(4)(ii) of this section, when a single MA organization offers an MA regional plan in each MA region in the year, but only if there was not a national plan offered in each region in the previous year. Funding under this paragraph is only available with respect to any individual MA organization for a single year, but may be made available to more than one such organization in the same year.

(B) *MA Regional Plans*. Subject to paragraph (f)(4)(i)(C) of this section, for an increased amount under paragraph (f)(4)(iv) of this section for an MA regional plan offered in an MA region that did not have any MA regional plan offered in the prior year.

(C) *Limitation on MA regional plan funding in case of national plan*. There will be no payment adjustment under paragraph (f)(4)(iii) of this section for a year for which a national bonus payment is made under paragraph (f)(4)(ii) of this section.

(ii) *National bonus payment*. The national bonus payment under this paragraph will—

(A) Be available to an MA organization only if the organization offers MA regional plans in every MA region;

(B) Be available for all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and

(C) Be subject to amounts available under paragraph (f)(3) of this section for a year and be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization.

(iii) *Regional payment adjustment*—(A) *General rule*. The increased amount under this paragraph for an MA regional plan in an MA region for a year must be an amount, determined by CMS, based on the bid submitted for that plan (or plans) and will be available to all MA regional plans offered in that region and year. That amount

may be based on the mean, mode, or median or other measure of those bids and may vary from region to region. CMS will not limit the number of plans or bids in a region.

(B) *Multi-year funding*. Subject to amounts available under paragraph (f)(3) of this section, funding will be available for a period determined by CMS.

(C) *Application to all plans in a region*. Funding under this paragraph for an MA region will be made available for all MA regional plans offered in the region.

(D) *Limitation on availability of plan retention funding in next year*. If plans receive plan entry funding in a year, plans in that region are prohibited from receiving plan retention funding in the following year.

(iv) *Application*. Any additional payment under this section provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(5) *Plan retention funding*—(i) *General rule*. Funding is available under this paragraph for a year with respect to MA regional plans offered in an MA region for the increased amount specified in paragraph (f)(5)(ii) of this section but only if the region meets the requirements of paragraphs (f)(5)(iii)(A), (f)(5)(iii)(B), (f)(5)(iii)(C) and (f)(5)(iii)(E) of this section.

(ii) *Payment increase*. The increased amount under this paragraph for an MA regional plan in an MA region for a year will be an amount, determined by CMS, that does not exceed the greater of—

(A) 3 percent of the benchmark amount applicable in the region; or

(B) The amount as (when added to the benchmark amount applicable to the region) will result in the ratio of-

(*1*) That additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i)of the Act, ''the risk-adjusted benchmark amount'' for the region and year, to the adjusted average per capita cost for the region and year, as estimated by CMS under section 1876(a)(4) of the Act and adjusted as appropriate for the purpose of risk adjustment; being equal to—

(*2*) The weighted average of those benchmark amounts for all the regions and that year, to the average per capita cost for the United States and that year, as estimated by CMS under section 1876(a)(4)of the Act and adjusted as appropriate for the purpose of risk adjustment.

(iii) *Regional requirements*. The requirements of this paragraph for an MA region for a year are as follows:

(A) *Notification of plan exit*. CMS has received notice (as specified by CMS), before a new contract year, that one or more MA regional plans that were offered in the region in the previous year will not be offered in the succeeding year.

(B) *Regional plans available from fewer than two MA organizations in the region*. CMS determines that if the plans referred to in paragraph (f)(5)(iii)(A) of this section are not offered in the year, fewer than two MA organizations will be offering MA regional plans in the region in the year involved.

(C) *Percentage enrollment in MA regional plans below national average*. For the previous year, CMS determines that the average percentage of MA eligible individuals residing in the region who are enrolled in MA regional plans is less than the average percentage of those individuals in the United States enrolled in those plans.

(D) *Application*. Any additional payment under this paragraph provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(E) *2–consecutive-year limitation*. In no case will plan retention funding be available under this paragraph in an MA region for more than 2 consecutive years.

[70 FR 4732, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

Subpart K—Contracts With Medicare Advantage Organizations

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§ 422.500 Scope and definitions.

(a) *Scope.* This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

(b) *Definitions.* For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the MA organization's enrollees by hospitals and other providers, and by MA organization staff, medical groups, or independent practice associations, or by any combination of those entities.

Clean claim means—

(1) A claim that has no defect, impropriety, lack of any required substantiating documentation (consistent with § 422.310(d)) or particular circumstance requiring special treatment that prevents timely payment; and

(2) A claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between an MA organization (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into an acceptable written arrangement with an MA organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

Party in interest includes the following:

(1) Any director, officer, partner, or employee responsible for management or administration of an MA organization.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of an MA organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law.

(4) Any entity in which a person described in paragraph (1), (2), or (3) of this definition:

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with, the MA organization.

(6) Any spouse, child, or parent of an individual described in paragraph (1), (2), or (3) of this definition.

Related entity means any entity that is related to the MA organization by common ownership or control and—

(1) Performs some of the MA organization's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the MA organization at a cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of ''business transaction'' that, during any fiscal year of

the MA organization, have a total value that exceeds $25,000 or 5 percent of the MA organization's total operating expenses, whichever is less.

[65 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000; 70 FR 4736, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.501 Application requirements.

(a) *Scope*. This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan.

(b) *Completion of an application*. (1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application, in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract; or

(ii) For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, the requirements described in this part.

(c) *Responsibility for making determinations*. (1) CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plans meet the requirements of this part.

(2) A CMS determination that an entity is qualified to act as an MA organization is distinct from the bid negotiation that occurs under subpart F of this part and such negotiation is not subject to the appeals provisions included in subpart N of this part.

(d) *Resubmittal of application*. An application that has been denied by CMS may not be resubmitted for 4 months after the date of the notice from CMS denying the application.

(e) *Disclosure of application information under the Freedom of Information Act*. An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5. Any final decisions as to whether material is privileged is the final decision of the Secretary.

[70 FR 4736, Jan. 28, 2005]

§ 422.502 Evaluation and determination procedures.

(a) *Basis for evaluation and determination*. (1) CMS evaluates an application for an MA contract on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits, public hearings, and any other appropriate procedures.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets the applicable requirements of § 422.501.

(b) *Use of information from a prior contracting period*. If an MA organization has failed to comply with the terms of a previous contract with CMS under title XVIII of the Act, or has failed to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the contract applicant meets all of the current requirements.

(c) *Notice of determination*. Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract under this part of its determination and the basis for the determination. The determination is one of the following:

(1) *Approval of application*. If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as an MA organization.

(2) *Intent to deny*. (i)If CMS finds that the applicant does not appear to be

able to meet the requirements for an MA organization and/or has not provided enough information to evaluate the application, CMS gives the contract applicant notice of intent to deny the application for an MA contract and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the intent to deny notice, the contract applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(3) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act;

(ii) The reasons why the applicant is not qualified; and

(iii) The applicant's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(d) *Oversight of continuing compliance.* (1) CMS oversees an MA organization's continued compliance with the requirements for an MA organization.

(2) If an MA organization no longer meets those requirements, CMS terminates the contract in accordance with § 422.510.

[70 FR 4736, Jan. 28, 2005]

§ 422.503 General provisions.

(a) *Basic rule.* In order to qualify as an MA organization, enroll beneficiaries in any MA plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an MA organization must enter into a contract with CMS.

(b) *Conditions necessary to contract as an MA organization.* Any entity seeking to contract as an MA organization must:

(1) Complete an application as described in § 422.501.

(2) Be licensed by the State as a risk bearing entity in each State in which it seeks to offer an MA plan as defined in § 422.2.

(3) Meet the minimum enrollment requirements of § 422.514, unless waived under § 422.514(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the MA organization's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) To operate a quality improvement program and have an agreement for external quality review as required under this part.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the MA organization, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the MA organization.

(v) Insurance policies or other arrangements, secured and maintained by the MA organization and approved by CMS to insure the MA organization against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) A compliance plan that consists of the following:

(A) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(B) The designation of a compliance officer and compliance committee that are accountable to senior management.

(C) Effective training and education between the compliance officer and organization employees.

(D) Effective lines of communication between the compliance officer and the organization's employees.

(E) Enforcement of standards through well-publicized disciplinary guidelines.

(F) Procedures for internal monitoring and auditing.

(G) Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's MA contract.

(*1*) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(*2*) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(H) For MA-PDs, A comprehensive fraud and abuse plan to detect and prevent fraud, waste, and abuse as specified at § 423.504(b)(4)(vi)(H) of this chapter.

(5) Not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(6) The MA organization's contract must not have been non-renewed under § 422.506 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing MA payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(c) *Contracting authority*. Under the authority of section 1857(c)(5) of the Act, CMS may enter into contracts under this part without regard to Federal and Departmental acquisition regulations set forth in title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections*. (1) CMS annually audits the financial records (including data relating to Medicare utilization, costs, and computation of the bid) of at least one-third of the MA organizations offering MA plans. These auditing activities are subject to monitoring by the Comptroller General.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS has the right to:

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the MA contract;

(ii) Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and

(iii) Audit and inspect any books, contracts, and records of the MA organization that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts*. The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005, and amended at 70 FR 4737, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.504 Contract provisions.

The contract between the MA organization and CMS must contain the following provisions:

(a) *Agreement to comply with regulations and instructions*. The MA organization agrees to comply with all the applicable requirements and conditions set forth in this part and in general instructions. An MA organization's compliance with paragraphs (a)(1) through (a)(13) of this section is material to performance of the contract. The MA organization agrees—

(1) To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(2) That it will comply with the prohibition in § 422.110 on discrimination in beneficiary enrollment.

(3) To provide—

(i) The basic benefits as required under § 422.101 and, to the extent applicable, supplemental benefits under § 422.102; and

(ii) Access to benefits as required under subpart C of this part;

(iii) In a manner consistent with professionally recognized standards of health care, all benefits covered by Medicare.

(4) To disclose information to beneficiaries in the manner and the form prescribed by CMS as required under § 422.111;

(5) To operate a quality assurance and performance improvement program and have an agreement for external quality review as required under subpart D of this part;

(6) To comply with all applicable provider requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans;

(7) To comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals;

(8) To comply with the reporting requirements in § 422.516 and the requirements in § 422.310 for submitting data to CMS;

(9) That it will be paid under the contract in accordance with the payment rules in subpart G of this part;

(10) To develop its annual bid, and submit all required information on premiums, benefits, and cost-sharing by not later than the first Monday in June, as provided in subpart F of this part;

(11) That its contract may not be renewed or may be terminated in accordance with this subpart and subpart N of this part.

(12) To comply with all requirements that are specific to a particular type of MA plan, such as the special rules for private fee-for-service plans in §§ 422.114 and 422.216 and the MSA requirements in §§ 422.56, 422.103, and 422.262; and

(13) To comply with the confidentiality and enrollee record accuracy requirements in § 422.118.

(14) An MA organization's compliance with paragraphs (a)(1) through (a)(13) and (c) of this section is material to performance of the contract.

(b) *Communication with CMS*. The MA organization must have the capacity to communicate with CMS electronically.

(c) *Prompt payment*. The MA organization must comply with the prompt payment provisions of § 422.520 and with instructions issued by CMS, as they apply to each type of plan included in the contract.

(d) *Maintenance of records*. The MA organization agrees to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that—

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid) of MA organizations.

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the MA organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the bid proposal.

(v) Establish component rates of the bid for determining additional and supplementary benefits.

(vi) Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and

(2) Include at least records of the following:

(i) Ownership and operation of the MA organization's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other action.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Schedules of charges for the MA organization's fee-for-service patients.

(viii) Matters pertaining to costs of operations.

(ix) Amounts of income received by source and payment.

(x) Cash flow statements.

(xi) Any financial reports filed with other Federal programs or State authorities.

(e) *Access to facilities and records.* The MA organization agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the MA organization; and

(iii) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the MA organization, related entity, contractor, subcontractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The MA organization agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MA organization at least 30 days before the normal disposition date;

(ii) There has been a termination, dispute, or allegation of fraud or similar fault by the MA organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, fraud, or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the MA organization at any time.

(f) *Disclosure of information.* The MA organization agrees to submit—

(1) To CMS, certified financial information that must include the following:

(i) Such information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Such information as CMS may require pertaining to the disclosure of ownership and control of the MA organization.

(2) To CMS, all information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:

(i) The benefits covered under an MA plan;

(ii) The MA monthly basic beneficiary premium and MA monthly supplemental beneficiary premium, if any, for the plan or in the case of an MSA plan, the MA monthly MSA premium.

(iii) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) Information on health outcomes;

(D) The recent record regarding compliance of the plan with requirements of this part, as determined by CMS; and

(E) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among MA plans and traditional Medicare;

(v) Information about beneficiary appeals and their disposition;

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;

(vii) To CMS, any other information deemed necessary by CMS for the administration or evaluation of the Medicare program.

(3) To its enrollees all informational requirements under § 422.64 and, upon an enrollee's, request the financial disclosure information required under § 422.516.

(g) *Beneficiary financial protections.* The MA organization agrees to comply with the following requirements:

(1) Each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the MA organization. To meet this requirement, the MA organization must—

(i) Ensure that all contractual or other written arrangements with providers prohibit the organization's providers from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the MA organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA organization, to provide services to the organization's beneficiary enrollees.

(2) The MA organization must provide for continuation of enrollee health care benefits—

(i) For all enrollees, for the duration of the contract period for which CMS payments have been made; and

(ii) For enrollees who are hospitalized on the date its contract with CMS terminates, or, in the event of an insolvency, through discharge.

(3) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the MA organization may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The MA organization agrees to comply with-

(1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et. seq.), and the anti-kickback statute (section 1128B(b)) of the Act); and

(2) HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164.

(i) *MA organization relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the MA organization may have with related entities, contractors, or subcontractors, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The MA organization agrees to require all related entities, contractors, or subcontractors to agree that—

(i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s)

involving transactions related to the MA contract; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period will exist through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between MA organizations and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the obligation of the MA organization.

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with the requirements set forth at paragraph (i)(4)of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the MA organization's contractual obligations.

(4) If any of the MA organizations' activities or responsibilities under its contract with CMS are delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or provider:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA organization determine that such parties have not performed satisfactorily.

(iii) Written arrangements must specify that the performance of the parties is monitored by the MA organization on an ongoing basis.

(iv) Written arrangements must specify that either—

(A) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the MA organization; or

(B) The credentialing process will be reviewed and approved by the MA organization and the MA organization must audit the credentialing process on an ongoing basis.

(v) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Medicare laws, regulations, and CMS instructions.

(5) If the MA organization delegates selection of the providers, contractors, or subcontractor to another organization, the MA organization's written arrangements with that organization must state that the CMS-contracting MA organization retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The MA organization agrees to include in the contract such other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

(l) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart G of this part, the MA organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data include specified enrollment information, encounter

data, and other information that CMS may specify.

(1) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an MA plan offered by the organization and the information relied upon by CMS in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.

(2) The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the data it submits under § 422.310 are accurate, complete, and truthful.

(3) If such data are generated by a related entity, contractor, or subcontractor of an MA organization, such entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data.

(4) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission is accurate, complete, and truthful and fully conforms to the requirements in § 422.254.

[63 FR 35099, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 64 FR 7980, Feb. 17, 1999; 65 FR 40327, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005 and amended at 70 FR 4737, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.505 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the MA organization and CMS and, for a contract that provides for coverage under an MSA plan, not earlier than January 1999.

(b) *Term of contract.* Each contract is for a period of at least 12 months.

(c) *Renewal of contract.* In accordance with § 422.506, contracts are renewed annually only if—

(1) CMS informs the MA organization that it authorizes a renewal; and

(2) The MA organization has not provided CMS with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although an MA organization may be determined qualified to renew its contract under this section, if the organization and CMS cannot reach agreement on the bid under subpart F of this part, no renewal will take place, and the failure to reach an agreement is not subject to the appeals provisions in subpart N of this part.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005 and amended at 70 FR 4737, Jan. 28, 2005]

§ 422.506 Nonrenewal of contract.

(a) *Nonrenewal by an MA organization.* (1) An MA organization may elect not to renew its contract with CMS as of the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If an MA organization does not intend to renew its contract, it must notify—

(i) CMS in writing, by the first Monday in June of the year in which the contract would end;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, and original Medicare and must receive CMS approval prior to issuance.

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community located in the MA organization's service area.

(3) CMS may accept a nonrenewal notice submitted after the first Monday in June if—

(i) The MA organization notifies its Medicare enrollees and the public in accordance with paragraph (a)(2)(ii) and (a)(2)(iii) of this section; and

(ii) Acceptance is not inconsistent with the effective and efficient administration of the Medicare program.

(4) If an MA organization does not renew a contract under this paragraph (a), CMS will not enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(b) *CMS decision not to renew.* (1) CMS may elect not to authorize renewal of a contract for any of the following reasons:

(i) The MA organization has not fully implemented or shown discernable progress in implementing quality improvement projects as defined in § 422.152(d).

(ii) For any of the reasons listed in § 422.510(a), which would also permit CMS to terminate the contract.

(iii) The MA organization has committed any of the acts in § 422.752(a) that would support the imposition of intermediate sanctions or civil money penalties under subpart O of this part.

(2) *Notice.* CMS provides notice of its decision whether to authorize renewal of the contract as follows:

(i) To the MA organization by May 1 of the contract year.

(ii) If CMS decides not to authorize a renewal of the contract, to the MA organization's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If CMS decides not to authorize a renewal of the contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

(3) *Notice of appeal rights.* CMS gives the MA organization written notice of its right to appeal the decision not to renew in accordance with § 422.644.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 67 FR 13289, Mar. 22, 2002; 70 FR 4737, Jan. 28, 2005]

§ 422.508 Modification or termination of contract by mutual consent.

(a) A contract may be modified or terminated at any time by written mutual consent.

(1) If the contract is terminated by mutual consent, except as provided in paragraph (b) of this section, the MA organization must provide notice to its Medicare enrollees and the general public as provided in § 422.512(b)(2) and (b)(3).

(2) If the contract is modified by mutual consent, the MA organization must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(b) If the contract terminated by mutual consent is replaced the day following such termination by a new MA contract, the MA organization is not required to provide the notice specified in paragraph (a)(1) of this section.

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons:

(1) The MA organization has failed substantially to carry out the terms of its contract with CMS.

(2) The MA organization is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part.

(3) CMS determines that the MA organization no longer meets the requirements of this part for being a contracting organization.

(4) There is credible evidence that the MA organization committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data.

(5) The MA organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists.

(6) The MA organization substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.

(7) The MA organization fails to provide CMS with valid data as required under § 422.310.

(8) The MA organization fails to implement an acceptable quality assessment and performance improvement program as required under subpart D of this part.

(9) The MA organization substantially fails to comply with the prompt payment requirements in § 422.520.

(10) The MA organization substantially fails to comply with the service access requirements in § 422.112 or § 422.114.

(11) The MA organization fails to comply with the requirements of § 422.208 regarding physician incentive plans.

(12) The MA organization substantially fails to comply with the marketing requirements in § 422.80.

(b) *Notice*. If CMS decides to terminate a contract for reasons other than the grounds specified in § 422.510(a)(5), it gives notice of the termination as follows:

(1) *Termination of contract by CMS*. (i) CMS notifies the MA organization in writing 90 days before the intended date of the termination.

(ii) The MA organization notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The MA organization notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

(2) *Immediate termination of contract by CMS*. (i) For terminations based on violations prescribed in § 422.510(a)(5), CMS notifies the MA organization in writing that its contract has been terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination.

(ii) CMS notifies the MA organization's Medicare enrollees in writing of CMS's decision to terminate the MA organization's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the MA contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining Medicare services, including alternative MA organizations in a similar geographic area and original Medicare.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the MA contract. This notice is published in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

(c) *Corrective action plan*—(1) *General*. Before terminating a contract for reasons other than the grounds specified in paragraph (a)(5) of this section, CMS provides the MA organization with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception*. If a contract is terminated under § 422.510(a)(5), the MA organization will not have the opportunity to submit a corrective action plan.

(d) *Appeal rights*. If CMS decides to terminate a contract, it sends written notice to the MA organization informing it of its termination appeal rights in accordance with subpart N of this part.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 70 FR 52027, Sept. 1, 2005]

§ 422.512 Termination of contract by the MA organization.

(a) *Cause for termination*. The MA organization may terminate the MA contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice*. The MA organization must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the MA organization is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the services area, including alternative MA plans, Medigap options,

original Medicare and must receive CMS approval.

(3) To the general public at least 60 days before the termination effective date by publishing an CMS-approved notice in one or more newspapers of general circulation in each community or county located in the MA organization's geographic area.

(c) *Effective date of termination*. The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the MA organization's notice of intent to terminate.

(d) *CMS's liability*. CMS's liability for payment to the MA organization ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization*. CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

[63 FR 35099, June 26, 1998, as amended at 67 FR 13288, Mar. 22, 2002]

§ 422.514 Minimum enrollment requirements.

(a) *Basic rule*. Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement—

(1) At least 5,000 individuals (or 1,500 individuals if the organization is a PSO) are enrolled for the purpose of receiving health benefits from the organization; or

(2) At least 1,500 individuals (or 500 individuals if the organization is a PSO) are enrolled for purposes of receiving health benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) (or, in the case of a PSO, the PSO meets the requirements in § 422.352(c)).

(3) Except as provided for in paragraph (b) of this section, an MA organization must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver*. (1) For a contract applicant or MA organization that does not meet the applicable requirement of paragraph (a) of this section at application for an MA contract or during the first 3 years of the contract, CMS may waive the minimum enrollment requirement as provided for below. To receive a waiver, a contract applicant or MA organization must demonstrate to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract. Factors that CMS takes into consideration in making this evaluation include the extent to which—

(i) The contract applicant or MA organization's management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section, or

(ii) The contract applicant or MA organization has the financial ability to bear financial risk under an MA contract. In determining whether an organization is capable of bearing risk, CMS considers factors such as the organization's management experience as described in paragraph (b)(1)(i) of this section and stop-loss insurance that is adequate and acceptable to CMS; and

(iii) The contract applicant or MA organization is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

(2) If an MA organization fails to meet the enrollment requirement in the first year, CMS may waive the minimum requirements for another year provided that the organization—

(i) Requests an additional minimum enrollment waiver no later than 120 days before the end of the first year;

(ii) Continues to demonstrate it is capable of administering and managing an MA contract and is able to manage the level of risk; and,

(iii) Demonstrates an acceptable marketing and enrollment process. Enrollment projections for the second

year of the waiver will become the organization's transitional enrollment standard.

(3) If an MA organization fails to meet the enrollment requirement in the second year, CMS may waive the minimum requirements for the third year only if the organization has attained the transitional enrollment standard as described in paragraph (b)(2)(iii) of this section.

(c) Failure to meet enrollment requirements. CMS may elect not to renew its contract with an MA organization that fails to meet the applicable enrollment requirement in paragraph (a) of this section

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000]

§ 422.516 Reporting requirements.

(a) *Required information.* Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the MA organization has a fiscally sound operation.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each MA organization must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in § 422.500) between the MA organization and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the MA organization and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the MA organization go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the MA organization.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the MA organization and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from an MA organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) with respect to a particular entity.

(d) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an MA organization in its offerings, the MA organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular MA organization) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The MA organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(e) *Loan information.* Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to Information*. Each MA organization must make the information reported to CMS under § 422.502(f)(1) available to its enrollees upon reasonable request.

§ 422.520 Prompt payment by MA organization.

(a) *Contract between CMS and the MA organization*.

(1) The contract between CMS and the MA organization must provide that the MA organization will pay 95 percent of the ''clean claims'' within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an MA private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider.

(2) The MA organization must pay interest on clean claims that are not paid within 30 days in accordance with sections 1816(c)(2)(B) and 1842(c)(2)(B).

(3) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request.

(b)(1) *Contracts between MA organizations and providers and suppliers*. Contracts or other written agreements between MA organizations and providers must contain a prompt payment provision, the terms of which are developed and agreed to by both the MA organization and the relevant provider.

(2) The MA organization is obligated to pay contracted providers under the terms of the contract between the MA organization and the provider.

(c) *Failure to comply*. If CMS determines, after giving notice and opportunity for hearing, that an MA organization has failed to make payments in accordance with paragraph (a) of this section, CMS may provide—

(1) For direct payment of the sums owed to providers, or MA private fee-for-service plan enrollees; and

(2) For appropriate reduction in the amounts that would otherwise be paid to the organization, to reflect the amounts of the direct payments and the cost of making those payments.

(d) A CMS decision to not conduct a hearing under paragraph (c) of this section does not disturb any potential remedy under State law for 1866(a)(1)(O) of the Act.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 70 FR 4738, Jan. 28, 2005]

§ 422.521 Effective date of new significant regulatory requirements.

CMS will not implement, other than at the beginning of a calendar year, requirements under this part that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute.

[68 FR 50858, Aug. 22, 2003]

§ 422.524 Special rules for RFB societies.

In order to participate as an MA organization, an RFB society—

(a) May not impose any limitation on membership based on any factor related to health status; and

(b) Must offer, in addition to the MA RFB plan, health coverage to individuals who are members of the church or convention or group of churches with which the society is affiliated, but who are not entitled to receive benefits from the Medicare program.

§ 422.527 Agreements with Federally qualified health centers.

The contract between the MA organization and CMS must specify that—

(a) The MA organization must pay a Federally qualified health center (FQHC) a similar amount to what it pays other providers for similar services.

(b) Under such a contract, the FQHC must accept this payment as payment in full, except for allowable cost sharing which it may collect.

(c) Financial incentives, such as risk pool payments or bonuses, and financial withholdings are not considered in determining the payments made by CMS under § 422.316(a).

[70 FR 4738, Jan. 28, 2005]

EFFECTIVE DATE NOTE: At 70 FR 52027, Sept. 1, 2005, § 422.527 was suspended, effective September 1, 2005 through January 1, 2006.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

SOURCE: 63 FR 35067, June 26, 1998, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to subpart L appear at 63 FR 35106, June 26, 1998.

§ 422.550 General provisions.

(a) *What constitutes change of ownership*—(1) *Partnership*. The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer*. Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation*. (i) The merger of the MA organization's corporation into another corporation or the consolidation of the MA organization with one or more other corporations, resulting in a new corporate body, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation into the MA organization's corporation, with the MA organization surviving, does not ordinarily constitute change of ownership.

(b) *Advance notice requirement*. (1) An MA organization that has a Medicare contract in effect and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The MA organization must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the MA organization fails to give CMS the required notice timely, it continues to be liable for capitation payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(c) *Novation agreement defined*. A novation agreement is an agreement among the current owner of the MA organization, the prospective new owner, and CMS—

(1) That is embodied in a document executed and signed by all three parties;

(2) That meets the requirements of § 422.552; and

(3) Under which CMS recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(d) *Effect of change of ownership without novation agreement*. Except to the extent provided in paragraph (b)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(e) *Effect of change of ownership with novation agreement*. If the MA organization submits a novation agreement that meets the requirements of § 422.552, and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract.

[60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 63 FR 52614, Oct. 1, 1998; 65 FR 40328, June 29, 2000; 70 FR 4738, Jan. 28, 2005]

§ 422.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement*. CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification*. The MA organization notifies CMS at least 60 days before the date of the proposed change of ownership. The MA organization also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement*. The MA organization submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination*. CMS determines that—

(i) The proposed new owner is in fact a successor in interest to the contract;

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program; and

(iii) The successor organization meets the requirements to qualify as an MA organization under subpart K of this part.

(b) *Provisions of a novation agreement*. (1) *Assumption of contract obligations*. The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement*. The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance*. (i) The previous owner must guarantee performance of the contract by the new owner during the contract period; or

(ii) The new owner must post a performance bond that is satisfactory to CMS.

(4) *Records access*. The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 70 FR 52027, Sept. 1, 2005]

§ 422.553 Effect of leasing of an MA organization's facilities.

(a) *General effect of leasing*. If an MA organization leases all or part of its facilities to another entity, the other entity does not acquire MA organization status under section 1876 of the Act.

(b) *Effect of lease of all facilities*. (1) If an MA organization leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as an MA organization, it must apply for and enter into a contract in accordance with subpart K of this part.

(c) *Effect of partial lease of facilities*. If the MA organization leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the MA organization to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 70 FR 52027, Sept. 1, 2005]

Subpart M—Grievances, Organization Determinations and Appeals

SOURCE: 63 FR 35107, June 26, 1998, unless otherwise noted.

§ 422.560 Basis and scope.

(a) *Statutory basis*. (1) Section 1852(f) of the Act provides that an MA organization must establish meaningful grievance procedures.

(2) Section 1852(g) of the Act establishes requirements that an MA organization must meet concerning organization determinations and appeals.

(3) Section 1869 of the Act specifies the amount in controversy needed to pursue a hearing and judicial review and authorizes representatives to act on behalf of individuals that seek appeals. These provisions are incorporated for MA appeals by section 1852(g)(5) of the Act and part 405 of this chapter.

(b) *Scope*. This subpart sets forth—

(1) Requirements for MA organizations with respect to grievance procedures, organization determinations, and appeal procedures.

(2) The rights of MA enrollees with respect to organization determinations, and grievance and appeal procedures.

(3) The rules concerning notice of noncoverage of inpatient hospital care.

(4) The rules that apply when an MA enrollee requests immediate QIO review of a determination that he or she no longer needs inpatient hospital care.

(c) *Relation to ERISA requirements*. Consistent with section 1857(i)(2) of the Act, provisions of this subpart may, to the extent applicable under regulations adopted by the Secretary of Labor, apply to claims for benefits under

group health plans subject to the Employee Retirement Income Security Act.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4738, Jan. 28, 2005]

§ 422.561 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under § 422.566(b). These procedures include reconsiderations by the MA organization, and if necessary, an independent review entity, hearings before ALJs, review by the Medicare Appeals Council (MAC), and judicial review.

Enrollee means an MA eligible individual who has elected an MA plan offered by an MA organization.

Grievance means any complaint or dispute, other than one that constitutes an organization determination, expressing dissatisfaction with any aspect of an MA organization's or provider's operations, activities, or behavior, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the appeal. Unless otherwise stated in this subpart, the representative will have all of the rights and responsibilities of an enrollee or party in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 68 FR 16667, Apr. 4, 2003; 70 FR 4738, Jan. 28, 2005]

§ 422.562 General provisions.

(a) *Responsibilities of the MA organization.* (1) An MA organization, with respect to each MA plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 422.564 for addressing issues that do not involve organization determinations;

(ii) A procedure for making timely organization determinations;

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve organization determinations; and

(2) An MA organization must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the MA organization; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) In accordance with subpart K of this part, if the MA organization delegates any of its responsibilities under this subpart to another entity or individual through which the organization provides health care services, the MA organization is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of MA enrollees.* In accordance with the provisions of this subpart, enrollees have the following rights:

(1) The right to have grievances between the enrollee and the MA organization heard and resolved, as described in § 422.564.

(2) The right to a timely organization determination, as provided under § 422.566.

(3) The right to request an expedited organization determination, as provided under § 422.570.

(4) If dissatisfied with any part of an organization determination, the following appeal rights:

(i) The right to a reconsideration of the adverse organization determination by the MA organization, as provided under § 422.578.

(ii) The right to request an expedited reconsideration, as provided under § 422.584.

(iii) If, as a result of a reconsideration, an MA organization affirms, in whole or in part, its adverse organization determination, the right to an automatic reconsidered determination made by an independent, outside entity contracted by CMS, as provided in § 422.592.

(iv) The right to an ALJ hearing if the amount in controversy is met, as provided in § 422.600.

(v) The right to request MAC review of the ALJ hearing decision, as provided in § 422.608.

(vi) The right to judicial review of the hearing decision if the amount in controversy is met, as provided in § 422.612.

(c) *Limits on when this subpart applies.* (1) If an enrollee receives immediate QIO review (as provided in § 422.622) of a determination of noncoverage of inpatient hospital care—

(i) The enrollee is not entitled to review of that issue by the MA organization; and

(ii) The QIO review decision is subject only to the appeal procedures set forth in parts 476 and 478 of this chapter.

(2) If an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal.

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act), apply under this subpart to the extent they are appropriate.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4738, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.564 Grievance procedures.

(a) *General rule.* Each MA organization must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any MA plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address organization determinations as defined in § 422.566(b). Upon receiving a complaint, an MA organization must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization (QIO) complaint process.* Under section 1154(a)(14) of the Act, the QIO must review beneficiaries' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the MA organization. For quality of care issues, an enrollee may file a grievance with the MA organization; file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the MA organization either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) The MA organization must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the organization receives the oral or written grievance.

(2) The MA organization may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the MA organization extends the deadline, it must immediately notify the enrollee in writing of the reasons for the delay.

(3) The MA organization must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in

writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* An MA organization must respond to an enrollee's grievance within 24 hours if:

(1) The complaint involves an MA organization's decision to invoke an extension relating to an organization determination or reconsideration.

(2) The complaint involves an MA organization's refusal to grant an enrollee's request for an expedited organization determination under § 422.570 or reconsideration under § 422.584.

(g) *Recordkeeping.* The MA organization must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the MA organization notified the enrollee of the disposition.

[68 FR 16667, Apr. 4, 2003, as amended at 70 FR 4738, Jan. 28, 2005]

§ 422.566 Organization determinations.

(a) *Responsibilities of the MA organization.* Each MA organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. The MA organization must have a standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572.

(b) *Actions that are organization determinations.* An organization determination is any determination made by an MA organization with respect to any of the following:

(1) Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the MA organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the MA organization.

(3) The MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.

(4) Discontinuation or reduction of a service if the enrollee believes that continuation of the services is medically necessary.

(5) Failure of the MA organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

(c) *Who can request an organization determination.* (1) Those individuals or entities who can request an organization determination are—

(i) The enrollee (including his or her authorized representative);

(ii) Any provider that furnishes, or intends to furnish, services to the enrollee; or

(iii) The legal representative of a deceased enrollee's estate.

(2) Those who can request an expedited determination are—

(i) An enrollee (including his or her authorized representative); or

(ii) A physician (regardless of whether the physician is affiliated with the MA organization).

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 68 FR 50858, Aug. 22, 2003; 70 FR 4739, Jan. 28, 2005]

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension.

(b) *Timeframe for requests for payment.* The MA organization must process requests for payment according to the ''prompt payment'' provisions set forth in § 422.520.

(c) *Written notice for MA organization denials.* If an MA organization decides to deny service or payment in whole or in part, or if an enrollee disagrees with an MA organization's decision to discontinue or reduce the level of care for an ongoing course of treatment, the organization must give the enrollee written notice of the determination.

(d) *Written notice for MA Organization denials.* If an enrollee requests an MA organization to provide an explanation of a practitioner's denial of an item or service, in whole or in part, the MA organization must give the enrollee a written notice.

(e) *Form and content of the MA organization notice.* The notice of any denial under paragraph (d) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(4)(i) For service denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

(ii) For payment denials, describe the standard reconsideration process and the rest of the appeal process; and

(5) Comply with any other notice requirements specified by CMS.

(f) *Effect of failure to provide timely notice.* If the MA organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

[65 FR 40329, June 29, 2000, as amended at 70 FR 4739, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the MA organization) may request that an MA organization expedite an organization determination involving the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or a physician must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the determination, as directed by the MA organization.

(2) A physician may provide oral or written support for a request for an expedited determination.

(c) *How the MA organization must process requests.* The MA organization must establish and maintain the following procedures for processing requests for expedited determinations:

(1) Establish an efficient and convenient means for individuals to submit oral or written requests. The MA organization must document all oral requests in writing and maintain the documentation in the case file.

(2) Promptly decide whether to expedite a determination, based on the following requirements:

(i) For a request made by an enrollee the MA organization must provide an expedited determination if it determines that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the MA organization must provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an MA organization denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in § 422.568 for a standard determination. The 14-day period begins with the day the MA organization receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the MA organization will process the request using the 14-day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite; and

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action on accepted request for expedited determination.* If an MA organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.

(f) *Prohibition of punitive action.* An MA organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited determination.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframe.* Except as provided in paragraph (b) of this section, an MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(b) *Extensions.* The MA organization may extend the 72–hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(d) *How the MA organization must request information from noncontract providers.* If the MA organization must receive medical information from noncontract providers, the MA organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited organization determination. Noncontract providers must

make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the MA organization in meeting the required timeframe. Regardless of whether the MA organization must request information from noncontract providers, the MA organization is responsible for meeting the timeframe and notice requirements of this section.

(e) *Content of the notice of expedited determination.* (1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a reconsideration;

(ii) Describe both the standard and expedited reconsideration processes, including the enrollee's right to request, and conditions for obtaining, an expedited reconsideration, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(f) *Effect of failure to provide a timely notice.* If the MA organization fails to provide the enrollee with timely notice of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.574 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee (including his or her authorized representative);

(b) An assignee of the enrollee (that is, a physician or other provider who has furnished a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other provider or entity (other than the MA organization) determined to have an appealable interest in the proceeding.

§ 422.576 Effect of an organization determination.

The organization determination is binding on all parties unless it is reconsidered under §§ 422.578 through 422.596 or is reopened and revised under § 422.616.

§ 422.578 Right to a reconsideration.

Any party to an organization determination (including one that has been reopened and revised as described in § 422.616) may request that the determination be reconsidered under the procedures described in § 422.582, which address requests for a standard reconsideration. An enrollee or physician (acting on behalf of an enrollee) may request an expedited reconsideration as described in § 422.584.

§ 422.580 Reconsideration defined.

A reconsideration consists of a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the MA organization or CMS obtains.

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination must ask for a reconsideration of the determination by making a written request to the MA organization that made the organization determination. The MA organization may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a party must file a request for reconsideration within 60 calendar days from the date of the notice of the organization determination.

(c) *Extending the time for filing a request*—(1) *General rule.* If a party shows good cause, the MA organization may extend the timeframe for filing a request for reconsideration.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination may file a request for reconsideration with the MA organization. The request for reconsideration and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed on time.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the organization determination, as described in § 422.574, and any other provider or entity (other than the MA organization) whose rights with respect to the organization determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawing a request.* The party who files a request for reconsideration may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4739, Jan. 28, 2005]

§ 422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the MA organization) may request that an MA organization expedite a reconsideration of a determination that involves the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *How to make a request.* (1) To ask for an expedited reconsideration, an enrollee or a physician acting on behalf of an enrollee must submit an oral or written request directly to the MA organization or, if applicable, to the entity responsible for making the reconsideration, as directed by the MA organization.

(2) A physician may provide oral or written support for a request for an expedited reconsideration.

(c) *How the MA organization must process requests.* The MA organization must establish and maintain the following procedures for processing requests for expedited reconsiderations:

(1) *Handling of requests.* The MA organization must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision.* Promptly decide on whether to expedite the reconsideration or follow the timeframe for standard reconsideration based on the following requirements:

(i) For a request made by an enrollee, the MA organization must provide an expedited reconsideration if it determines that applying the standard timeframe for reconsidering a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the MA organization must provide an expedited reconsideration if the physician indicates that applying the standard timeframe for conducting a reconsideration could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an MA organization denies a request for expedited reconsideration, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in § 422.590(a). The 30-day period begins the day the MA organization receives the request for expedited reconsideration.

(2) Give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the MA organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited reconsideration with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action following acceptance of a request.* If an MA organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590.

(f) *Prohibition of punitive action.* An MA organization may not take or

threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited reconsideration.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.586 Opportunity to submit evidence.

The MA organization must provide the parties to the reconsideration with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited reconsideration, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the MA organization must inform the parties of the conditions for submitting the evidence.

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. For extensions, the MA organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(2) If the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(b) *Standard reconsideration: Request for payment.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with § 422.618(a)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

(2) If the MA organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(c) *Effect of failure to meet timeframe for standard reconsideration.* If the MA organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a) or paragraph (b) of this section, this failure constitutes an affirmation of its adverse organization determination, and the MA organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2) and (b)(2) of this section.

(d) *Expedited reconsideration*—(1) *Timeframe.* Except as provided in paragraph (d)(2) of this section, an MA organization that approves a request for expedited reconsideration must complete

its reconsideration and give the enrollee (and the physician involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Extensions.* The MA organization may extend the 72–hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(3) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 3 calendar days.

(4) *How the MA organization must request information from noncontract providers.* If the MA organization must receive medical information from noncontract providers, the MA organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the MA organization in meeting the required timeframe. Regardless of whether the MA organization must request information from noncontract providers, the MA organization is responsible for meeting the timeframe and notice requirements.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the MA organization affirms, in whole or in part, its adverse expedited organization determination, the MA organization must submit a written explanation and the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(e) *Notification of enrollee.* If the MA organization refers the matter to the independent entity as described under this section, it must concurrently notify the enrollee of that action.

(f) *Failure to meet timeframe for expedited reconsideration.* If the MA organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (d) of this section, this failure constitutes an adverse reconsidered determination, and the MA organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (d) of this section.

(g) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in making the organization determination must conduct the reconsideration.

(2) When the issue is the MA organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000; 70 FR 4739, Jan. 28, 2005]

§ 422.592 Reconsideration by an independent entity.

(a) When the MA organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS.

(b) The independent outside entity must conduct the review as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract.

(c) When the independent entity conducts a reconsideration, the parties to the reconsideration are the same parties listed in § 422.582(d) who qualified during the MA organization's reconsideration, with the addition of the MA organization.

§ 422.594 Notice of reconsidered determination by the independent entity.

(a) *Responsibility for the notice.* When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions in understandable language;

(2) If the reconsidered determination is adverse (that is, does not completely reverse the MA organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy is $100 or more;

(3) Describe the procedures that a party must follow to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000]

§ 422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party other than the MA organization files a request for a hearing under the provisions of § 422.602, or unless the reconsidered determination is revised under § 422.616.

[65 FR 40331, June 29, 2000]

§ 422.600 Right to a hearing.

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with part 405 of this chapter.

(c) If the basis for the appeal is the MA organization's refusal to provide services, CMS uses the projected value of those services to compute the amount remaining in controversy.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4740, Jan. 28, 2005]

§ 422.602 Request for an ALJ hearing.

(a) *How and where to file a request.* A party must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request.* Except when an ALJ extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 days of the date of the notice of a reconsidered determination. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020.

(c) *Parties to a hearing.* The parties to a hearing are the parties to the reconsideration, the MA organization, and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(d) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 422.600, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 422.600, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4740, Jan. 28, 2005]

§ 422.608 Medicare Appeals Council (MAC) review.

Any party to the hearing, including the MA organization, who is dissatisfied with the ALJ hearing decision, may request that the MAC review the

ALJ's decision or dismissal. The regulations under part 405 of this chapter regarding MAC review apply to matters addressed by this subpart to the extent that they are appropriate.

[70 FR 4740, Jan. 28, 2005]

§ 422.612 Judicial review.

(a) *Review of ALJ's decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of an ALJ's decision if—

(1) The Board denied the party's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review.* In order to request judicial review, a party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405 of this chapter for a description of the procedures to follow in requesting judicial review.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 65 FR 40331, June 29, 2000; 70 FR 4740, Jan. 28, 2005]

§ 422.616 Reopening and revising determinations and decisions.

(a) An organization or reconsidered determination made by an MA organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 405 of this chapter.

(b) Reopening may be at the instigation of any party.

(c) The filing of a request for reopening does not relieve the MA organization of its obligation to make payment or provide services as specified in § 422.618.

(d) Once an entity issues a revised determination or decision, any party may file an appeal.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 70 FR 4740, Jan. 28, 2005]

§ 422.618 How an MA organization must effectuate standard reconsidered determinations or decisions.

(a) *Reversals by the MA organization*—(1) *Requests for service.* If, on reconsideration of a request for service, the MA organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(a)(1)).

(2) *Requests for payment.* If, on reconsideration of a request for payment, the MA organization completely reverses its organization determination, the organization must pay for the service no later than 60 calendar days after the date the MA organization receives the request for reconsideration.

(b) *Reversals by the independent outside entity.* (1) *Requests for service.* If, on reconsideration of a request for service, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Requests for payment.* If, on reconsideration of a request for payment, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must pay for the service no later than 30 calendar days from the

date it receives notice reversing the organization determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the MA organization or the independent outside entity.*—(1) *General rule.* If the independent outside entity's determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the MA organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision or that it has appealed the decision.

(2) *Effectuation exception when the MA organization files an appeal with the Medicare Appeals Council.* If the MA organization requests Medicare Appeals Council (the Board) review consistent with § 422.608, the MA organization may await the outcome of the review before it pays for, authorizes, or provides the service under dispute. A MA organization that files an appeal with the Board must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40331, June 29, 2000; 68 FR 50858, Aug. 22, 2003]

§ 422.619 How an MA organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the MA organization.* If on reconsideration of an expedited request for service, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(d)(2)).

(b) *Reversals by the independent outside entity.* If the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the MA organization or the independent outside entity*—(1) *General rule.* If the independent outside entity's expedited determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Effectuation exception when the MA organization files an appeal with the Medicare Appeals Council.* If the MA organization requests Medicare Appeals Council (the Board) review consistent with § 422.608, the MA organization may await the outcome of the review before it authorizes or provides the service under dispute. A MA organization that files an appeal with the Board must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

[65 FR 40331, June 29, 2000, as amended at 68 FR 50859, Aug. 22, 2003]

§ 422.620 How enrollees of MA organizations must be notified of noncovered inpatient hospital care.

(a) *Enrollee's entitlement.* (1) Where an MA organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.113), the MA organization (or hospital that has been delegated the authority to make the discharge decision) must provide a written notice of noncoverage when—

(i) The beneficiary disagrees with the discharge decision; or

(ii) The MA organization (or the hospital that has been delegated the authority to make the discharge decision) is not discharging the individual but no longer intends to continue coverage of the inpatient stay.

(2) An enrollee is entitled to coverage until at least noon of the day after such notice is provided. If QIO review is requested under § 422.622, coverage is extended as provided in that section.

(b) *Physician concurrence required.* Before discharging an individual or changing the level of care in an inpatient hospital setting, the MA organization must obtain the concurrence of the physician who is responsible for the enrollee's inpatient care.

(c) *Notice to the enrollee.* When applicable, the written notice of non-coverage must be issued no later than the day before hospital coverage ends. The written notice must include the following elements:

(1) The reason why inpatient hospital care is no longer needed or covered;

(2) The effective date and time of the enrollee's liability for continued inpatient care;

(3) The enrollee's appeal rights;

(4) If applicable, the new lower level of care being covered in the hospital setting; and

(5) Any additional information specified by CMS.

[68 FR 16667, Apr. 4, 2003, as amended at 70 FR 4740, Jan. 28, 2005]

EFFECTIVE DATE NOTE: At 68 FR 20349, Apr. 4, 2003, § 422.620 was revised. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget

§ 422.622 Requesting immediate QIO review of noncoverage of inpatient hospital care.

(a) *Enrollee's right to review or reconsideration.* (1) An enrollee who wishes to appeal a determination by an MA organization or hospital that inpatient care is no longer necessary must request immediate QIO review of the determination in accordance with paragraph (b) of this section. An enrollee who requests immediate QIO review may remain in the hospital with no additional financial liability as specified in paragraph (c) of this section.

(2) An enrollee who fails to request immediate QIO review in accordance with the procedures in paragraph (b) of this section may request expedited reconsideration by the MA organization as described in § 422.584, but the financial liability rules of paragraph (c) of this section do not apply.

(b) *Procedures enrollee must follow.* For the immediate QIO review process, the following rules apply:

(1) The enrollee must submit the request for immediate review—

(i) To the QIO that has an agreement with the hospital under parts 476 and 478 of this chapter.

(ii) In writing or by telephone; and

(iii) By noon of the first working day after he or she receives written notice that the MA organization or hospital has determined that the hospital stay is no longer necessary.

(2) On the date it receives the enrollee's request, the QIO must notify the MA organization that the enrollee has filed a request for immediate review.

(3) The MA organization must supply any information that the QIO requires to conduct its review and must make it available, by phone or in writing, by the close of business of the first full working day immediately following the day the enrollee submits the request for review.

(4) In response to a request from the MA organization, the hospital must submit medical records and other pertinent information to the QIO by close of business of the first full working day immediately following the day the organization makes its request.

(5) The QIO must solicit the views of the enrollee who requested the immediate QIO review.

(6) The QIO must make a determination and notify the enrollee, the hospital, and the MA organization by close of business of the first working day after it receives all necessary information from the hospital, or the organization, or both.

(c) *Liability for hospital costs*—(1) *When the MA organization determines that hospital services are not, or are no longer, covered.* (i) Except as provided in paragraph (c)(1)(ii) of this section, if

the MA organization authorized coverage of the inpatient admission directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(c)), the organization continues to be financially responsible for the costs of the hospital stay when a timely appeal is filed under paragraph (a)(1) of this section until noon of the calendar day following the day the QIO notifies the enrollee of its review determination. If coverage of the hospital admission was never approved by the MA organization (or the admission does not constitute emergency or urgently needed care, as described in §§ 422.2 and 422.112(c)), the MA organization is liable for the hospital costs only if it is determined on appeal that the hospital stay should have been covered under the MA plan.

(ii) The hospital may not charge the MA organization (or the enrollee) if—

(A) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate QIO review; and

(B) The QIO upholds the noncoverage determination made by the MA organization.

(2) *When the hospital determines that hospital services are no longer required.* If the hospital determines that inpatient hospital services are no longer necessary, and the enrollee could not reasonably be expected to know that the services would not be covered, the hospital may not charge the enrollee for inpatient services received before noon of the calendar day following the day the QIO notifies the enrollee of its review determination.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 70 FR 4740, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.624 Notifying enrollees of termination of provider services.

(a) *Applicability.* (1) For purposes of §§ 422.624 and 422.626, the term provider includes home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs).

(2) *Termination of service defined.* For purposes of this section and § 422.626, a termination of service is the discharge of an enrollee from covered provider services, or discontinuation of covered provider services, when the enrollee has been authorized by the MA organization, either directly or by delegation, to receive an ongoing course of treatment from that provider. Termination includes cessation of coverage at the end of a course of treatment preauthorized in a discrete increment, regardless of whether the enrollee agrees that such services should end.

(b) *Advance written notification of termination.* Prior to any termination of service, the provider of the service must deliver valid written notice to the enrollee of the MA organization's decision to terminate services. The provider must use a standardized notice, required by the Secretary, in accordance with the following procedures—

(1) *Timing of notice.* The provider must notify the enrollee of the MA organization's decision to terminate covered services no later than two days before the proposed end of the services. If the enrollee's services are expected to be fewer than two days in duration, the provider should notify the enrollee at the time of admission to the provider. If, in a non-institutional setting, the span of time between services exceeds two days, the notice should be given no later than the next to last time services are furnished.

(2) *Content of the notice.* The standardized termination notice must include the following information:

(i) The date that coverage of services ends.

(ii) The date that the enrollee's financial liability for continued services begins.

(iii) A description of the enrollee's right to a fast-track appeal under § 422.626, including information about how to contact an independent review entity (IRE), an enrollee's right (but not obligation) to submit evidence showing that services should continue, and the availability of other MA appeal procedures if the enrollee fails to meet the deadline for a fast-track IRE appeal.

(iv) The enrollee's right to receive detailed information in accordance with § 422.626 (e)(1) and (2).

(v) Any other information required by the Secretary.

(c) *When delivery of notice is valid.*

Delivery of the termination notice is not valid unless—

(1) The enrollee (or the enrollee's authorized representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

(2) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(d) *Financial liability for failure to deliver valid notice.* An MA organization is financially liable for continued services until 2 days after the enrollee receives valid notice as specified under paragraph (c) of this section. An enrollee may waive continuation of services if he or she agrees with being discharged sooner than 2 days after receiving the notice.

EFFECTIVE DATE NOTE: At 68 FR 20349, Apr. 4, 2003, § 422.624 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(a) *Enrollee's right to a fast-track appeal of an MA organization's termination decision.* An enrollee of an MA organization has a right to a fast-track appeal of an MA organization's decision to terminate provider services.

(1) An enrollee who desires a fast-track appeal must submit a request for an appeal to an IRE under contract with CMS, in writing or by telephone, by noon of the first day after the day of delivery of the termination notice. If, due to an emergency, the IRE is closed and unable to accept the enrollee's request for a fast-track appeal, the enrollee must file a request by noon of the next day that the IRE is open for business.

(2) When an enrollee fails to make a timely request to an IRE, he or she may request an expedited reconsideration by the MA organization as described in § 422.584.

(3) If, after delivery of the termination notice, an enrollee chooses to leave a provider or discontinue receipt of covered services on or before the proposed termination date, the enrollee may not later assert fast-track IRE appeal rights under this section relative to the services or expect the services to resume, even if the enrollee requests an appeal before the discontinuation date in the termination notice.

(b) *Coverage of provider services.* Coverage of provider services continues until the date and time designated on the termination notice, unless the enrollee appeals and the IRE reverses the MA organization's decision. If the IRE's decision is delayed because the MA organization did not timely supply necessary information or records, the MA organization is liable for the costs of any additional coverage required by the delayed IRE decision. If the IRE finds that the enrollee did not receive valid notice, coverage of provider services by the MA organization continues until at least two days after valid notice has been received. Continuation of coverage is not required if the IRE determines that coverage could pose a threat to the enrollee's health or safety.

(c) *Burden of proof.* When an enrollee appeals an MA organization's decision to terminate services to an IRE, the burden of proof rests with the MA organization to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) To meet this burden, the MA organization must supply any and all information that an IRE requires to sustain the MA organization's termination decision, consistent with paragraph (e) of this section.

(2) The enrollee may submit evidence to be considered by an IRE in making its decision.

(3) The MA organization or an IRE may require an enrollee to authorize release to the IRE of his or her medical records, to the extent that the records are necessary for the MA organization to demonstrate the correctness of its decision or for an IRE to determine the appeal.

(d) *Procedures an IRE must follow.* (1) On the date an IRE receives the enrollee's request for an appeal, the IRE

must immediately notify the MA organization and the provider that the enrollee has filed a request for a fast-track appeal, and of the MA organization's responsibility to submit documentation consistent with paragraph (e)(3) of this section.

(2) When an enrollee requests a fast-track appeal, the IRE must determine whether the provider delivered a valid notice of the termination decision, and whether a detailed notice has been provided, consistent with paragraph (e)(1) of this section.

(3) The IRE must notify CMS about each case in which it determines that improper notification occurs.

(4) Before making its decision, the IRE must solicit the enrollee's views regarding the reason(s) for termination of services as specified in the detailed written notice provided by the MA organization, or regarding any other reason that the IRE uses as the basis of its review determination.

(5) An IRE must make a decision on an appeal and notify the enrollee, the MA organization, and the provider of services, by close of business of the day after it receives the information necessary to make the decision. If the IRE does not receive the information needed to sustain an MA organization's decision to terminate services, it may make a decision on the case based on the information at hand, or it may defer its decision until it receives the necessary information. If the IRE defers its decision, coverage of the services by the MA organization would continue until the decision is made, consistent with paragraph (b) of this section, but no additional termination notice would be required.

(e) *Responsibilities of the MA organization.* (1) When an IRE notifies an MA organization that an enrollee has requested a fast-track appeal, the MA organization must send a detailed notice to the enrollee by close of business of the day of the IRE's notification. The detailed termination notice must include the following information:

(i) A specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction or other Medicare policy including citations, to the applicable Medicare policy rules, or the information about how the enrollee may obtain a copy of the Medicare policy from the MA organization.

(iii) Any applicable MA organization policy, contract provision, or rationale upon which the termination decision was based.

(iv) Facts specific to the enrollee and relevant to the coverage determination that are sufficient to advise the enrollee of the applicability of the coverage rule or policy to the enrollee's case.

(v) Any other information required by CMS.

(2) Upon an enrollee's request, the MA organization must provide the enrollee a copy of, or access to, any documentation sent to the IRE by the MA organization, including records of any information provided by telephone. The MA organization may charge the enrollee a reasonable amount to cover the costs of duplicating the information for the enrollee and/or delivering the documentation to the enrollee. The MA organization must accommodate such a request by no later than close of business of the first day after the day the material is requested.

(3) Upon notification by the IRE of a fast-track appeal, the MA organization must supply any and all information, including a copy of the notice sent to the enrollee, that the IRE needs to decide on the appeal. The MA organization must supply this information as soon as possible, but no later than by close of business of the day that the IRE notifies the MA organization that an appeal has been received from the enrollee. The MA organization must make the information available by phone (with a written record made of what is transmitted in this manner) and/or in writing, as determined by the IRE.

(4) An MA organization is financially responsible for coverage of services as provided in paragraph (b) of this section, regardless of whether it has delegated responsibility for authorizing coverage or termination decisions to its providers.

(5) If an IRE reverses an MA organization's termination decision, the MA

organization must provide the enrollee with a new notice consistent with § 422.624(b).

(f) *Reconsiderations of IRE decisions.* (1) If the IRE upholds an MA organization's termination decision in whole or in part, the enrollee may request, no later than 60 days after notification that the IRE has upheld the decision that the IRE reconsider its original decision.

(2) The IRE must issue its reconsidered determination as expeditiously as the enrollee's health condition requires but no later than within 14 days of receipt of the enrollee's request for a reconsideration.

(3) If the IRE reaffirms its decision, in whole or in part, the enrollee may to appeal the IRE's reconsidered determination to an ALJ, the MAC, or a federal court, as provided for under this subpart.

(4) If on reconsideration the IRE determines that coverage of provider services should terminate on a given date, the enrollee is liable for the costs of continued services after that date unless the IRE's decision is reversed on appeal. If the IRE's decision is reversed on appeal, the MA organization must reimburse the enrollee, consistent with the appealed decision, for the costs of any covered services for which the enrollee has already paid the MA organization or provider.

EFFECTIVE DATE NOTE: At 68 FR 20349, Apr. 4, 2003, § 422.626 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget

Subpart N—Medicare Contract Determinations and Appeals

SOURCE: 63 FR 35113, June 26, 1998, unless otherwise noted.

§ 422.641 Contract determinations.

This subpart establishes the procedures for making and reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part C of title XVIII of the Act.

(b) A determination to terminate a contract with an MA organization in accordance with § 422.510(a).

(c) A determination not to authorize a renewal of a contract with an MA organization in accordance with § 422.506(b).

§ 422.644 Notice of contract determination.

(a) When CMS makes a contract determination, it gives the MA organization written notice.

(b) The notice specifies—

(1) The reasons for the determination; and

(2) The MA organization's right to request reconsideration.

(c) For CMS-initiated terminations, CMS mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at § 422.510(a)(5), CMS immediately notifies the MA organization of its decision to terminate the organization's MA contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the MA organization by May 1 of the current contract year.

§ 422.646 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with §§ 422.648 through 422.658;

(b) A timely request for a hearing is filed under § 422.662; or

(c) The reconsideration decision is revised as a result of a reopening under § 422.696.

§ 422.648 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in § 422.641.

(b) CMS reconsiders the specified determinations if the contract applicant or the MA organization files a written request in accordance with § 422.650.

(c) Notice of any redetermination favorable to the MA organization applicant, including those resulting from a

hearing or Administrator review conducted under this subpart, must be issued by July 15 for the contract in question to be effective on January 1 of the following year.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40331, June 29, 2000; 70 FR 4741, Jan. 28, 2005]

§ 422.650 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or MA organization that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The MA organization or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40331, June 29, 2000]

§ 422.652 Opportunity to submit evidence.

CMS provides the MA organization or contract applicant and the CMS official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which an MA organization could choose to request a hearing as described at § 422.662, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

[65 FR 40332, June 29, 2000]

§ 422.654 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the MA organization subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

§ 422.656 Notice of reconsidered determination.

(a) CMS gives the MA organization or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings with respect to the contract applicant's qualifications to enter into, or the MA organization's qualifications to remain under, a contract with CMS under Part C of title XVIII of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the MA organization or contract applicant of its right to a hearing if it is dissatisfied with the determination.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000]

§ 422.658 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with § 422.662 or it is revised in accordance with § 422.696.

§ 422.660 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that has been determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part C of title XVIII of the Act.

(b) An MA organization whose contract with CMS has been terminated or has not been renewed as a result of a contract determination as provided in § 422.641.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000]

§ 422.662 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or MA organization that was the party

to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 422.660;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000]

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing with respect to a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with an MA organization until a hearing decision is reached and affirmed by the Administrator following review under § 422.692 in instances where an MA organization requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract will be consistent with the purpose of this part; and

(2) For such period as CMS and the MA organization agree.

(c) Exception: A contract terminated in accordance with § 422.510(a)(5) will be immediately terminated and will not be postponed if a hearing is requested.

§ 422.666 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 422.668 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 422.670 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer will give the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 422.672 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 422.674 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 422.672 may, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 422.676 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 422.678 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

§ 422.680 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 422.682 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 422.684 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

§ 422.686 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision has been issued.

§ 422.688 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 422.690 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 422.692, or reopened and revised in accordance with § 422.696.

§ 422.692 Review by the Administrator.

(a) *Request for review by Administrator*. An MA organization that has received a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 422.690(b).

(b) *Review by the Administrator*. The Administrator shall review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the MA organization, whether the termination decision should be upheld, reversed, or modified.

(c) *Decision by the Administrator*. The Administrator issues a written decision, and furnishes the decision to the MA organization requesting review.

§ 422.694 Effect of Administrator's decision.

A decision by the Administrator under section 422.692 is final and binding unless it is reopened and revised in accordance with § 422.696.

§ 422.696 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination*. CMS may reopen and revise an initial or reconsidered determination upon its own motion within one year of the date of the notice of determination.

(b) *Decision of hearing officer*. A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within one year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator*. A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within one year of the notice of the Administrator's decision.

(d) *Notices*. (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 422.698 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 422.662.

Subpart O—Intermediate Sanctions

SOURCE: 63 FR 35115, June 26, 1998, unless otherwise noted.

§ 422.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from $10,000 to $100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the MA organization for Medicare beneficiaries who enroll.

(4) Require the MA organization to suspend all marketing activities to Medicare beneficiaries for the MA plan subject to the intermediate sanctions.

(b) The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to recur.

§ 422.752 Basis for imposing sanctions.

(a) *All intermediate sanctions*. For the violations listed in this paragraph (a), we may impose one, or more, of the sanctions specified in § 422.750(a)(2), (a)(3), or (a)(4) on any MA organization that has a contract in effect. The MA organization may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to an MA enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to an MA enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on MA enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1854 of the Act and subpart F of this part.

(3) Expels or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity.

(6) Fails to comply with the requirements of § 422.206, which prohibits interference with practitioners' advice to enrollees.

(7) Fails to comply with § 422.216, which requires the organization to enforce the limit on balance billing under a private fee-for service plan.

(8) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If CMS makes a determination under § 422.510(a), CMS may impose the intermediate sanctions in § 422.750(a)(2) and (a)(4).

[63 FR 35115, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 69 FR 78338, Dec. 30, 2004; 70 FR 4741, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005]

§ 422.756 Procedures for imposing sanctions.

(a) *Notice of Sanction and opportunity to respond*—(1) *Notice of sanction.* Before imposing the intermediate sanctions specified in paragraph (c) of this section CMS—

(i) Sends a written notice to the MA organization stating the nature and basis of the proposed sanction; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the MA organization 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements described in § 422.752, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the MA organization. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the MA organization's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration.* If, consistent with paragraph (a)(2) of this section the MA organization submits a timely response to CMS's notice of sanction, CMS conducts an informal reconsideration that:

(1) Consists of a review of the evidence by an CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the MA organization a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions.* If CMS determines that an MA organization has acted or failed to act as specified in § 422.752 and affirms this determination in accordance with paragraph (b) of this section, CMS may—

(1) Require the MA organization to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned MA plan during the sanction period;

(2) In the case of a violation under § 422.752(a), suspend payments to the MA organization for Medicare beneficiaries enrolled in the sanctioned MA plan during the sanction period; and

(3) Require the MA organization to suspend all marketing activities for the sanctioned MA plan to Medicare enrollees.

(d) Effective date and duration of sanctions—(1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the MA organization timely seeks reconsideration under paragraph (b) of this section, on the date specified in the notice of CMS's reconsidered determination.

(2) *Exception.* If CMS determines that the MA organization's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS's reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the MA organization that CMS is satisfied that the basis for imposing the

sanction has been corrected and is not likely to recur.

(e) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with § 422.506(b)(2) and (b)(3), or terminate the contract in accordance with § 422.510.

(f) *Civil money penalties.* (1) If CMS determines that an MA organization has committed an act or failed to comply with a requirement described in § 422.752, CMS notifies the OIG of this determination, and also notifies OIG when CMS reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in paragraph (a) of § 422.752, or a determination under paragraph (b) of § 422.752 based upon a violation under § 422.510(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1003 of this chapter, the OIG may impose civil money penalties on the MA organization in accordance with part 1003 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 422.752(b) other than a determination based upon a violation under § 422.510(a)(4), CMS may impose civil money penalties on the MA organization in the amounts specified in § 422.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

[63 FR 35113, June 26, 1998, as amended at 68 FR 50859, Aug. 22, 2003; 70 FR 4741, Jan. 28, 2005]

§ 422.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 422.510(a), as described in § 422.752(b) excepting those determinations under § 422.510(a)(4), CMS may impose civil money penalties in addition to, or in place of, the sanctions that CMS may impose under § 422.756(c) in the following amounts:

(a) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Medicare Advantage enrollees—up to $25,000 for each determination.

(b) For each week that a deficiency remains uncorrected after the week in which the Medicare Advantage organization receives CMS' notice of the determination—up to $10,000.

(c) If CMS makes a determination that a MA organization has terminated its contract other than in a manner described under § 422.512 and that the MA organization has therefore failed to substantially carry out the terms of the contract—$250 per Medicare enrollee from the terminated MA plan or plans at the time the MA organization terminated its contract, or $100, 000, whichever is greater.

[69 FR 78338, Dec. 30, 2004, as amended at 70 FR 4741, Jan. 28, 2005]

§ 422.760 Other applicable provisions.

The provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

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AUTHORITY: Secs 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

SOURCE: 70 FR 4525, Jan. 28, 2005, unless otherwise noted.

Subpart A—General Provisions

§ 423.1 Basis and scope.

(a) Basis. (1) This part is based on the indicated provisions of the following sections of the Social Security Act:

1860D–1. Eligibility, enrollment, and information.

1860D–2. Prescription drug benefits.

1860D–3. Access to a choice of qualified prescription drug coverage.

1860D–4. Beneficiary protections for qualified prescription drug coverage.

1860D–11. PDP regions; submission of bids; plan approval.

1860D–12. Requirements for and contracts with prescription drug plan (PDP) sponsors.

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1860D–14. Premium and cost-sharing subsidies for low-income individuals.

1860D–15. Subsidies for Part D eligible individuals for qualified prescription drug coverage.

1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

1860D–21. Application to Medicare Advantage program and related managed care programs.

1860D–22. Special rules for Employer-Sponsored Programs

1860D–23. State pharmaceutical assistance programs.

1860D–24. Coordination requirements for plans providing prescription drug coverage.

1860D–31. Medicare prescription drug discount card and transitional assistance program.

1860D–41. Definitions; treatment of references to provisions in Part C.

1860D–42. Miscellaneous provisions.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.

Sec. 103 Medicaid amendments.

Sec. 104 Medigap.

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(b) *Scope*. This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS actuarial guidelines.

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Eligible fallback entity or fallback entity is defined at § 423.855.

Fallback prescription drug plan is defined at § 423.855.

Formulary means the entire list of Part D drugs covered by a Part D plan.

Full-benefit dual eligible individual has the meaning given the term at § 423.772, except where otherwise provided.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Group health plan is defined at § 423.882.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan has the meaning given the term in § 422.2 of this chapter.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium means the amount calculated under § 423.286 for Part D plans other than fallback prescription drug plans, and § 423.867(a) for fallback prescription drug plans.

PACE Plan means a plan offered by a PACE organization.

PACE organization is defined in § 460.6 of this chapter.

Part D eligible individual means an individual who meets the requirements at § 423.30(a).

Part D plan (or Medicare Part D plan) means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor refers to a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part. This includes fallback prescription drug plans.

Service area (Service area does not include facilities in which individuals are incarcerated.) means for—

(1) A prescription drug plan, an area established in § 423.112(a) within which access standards under § 423.120(a) are met;

(2) An MA-PD plan, an area that meets the definition of MA service area as described in § 422.2 of this chapter, and within which access standards under § 423.120(a) are met;

(3) A fallback prescription drug plan, the service area described in § 423.859(b);

(4) A PACE plan offering qualified prescription drug coverage, the service area described in § 460.22 of this chapter; and

(5) A cost plan offering qualified prescription drug coverage, the service area defined in § 417.1 of this chapter.

Subsidy-eligible individual means a full subsidy eligible individual (as defined at § 423.772) or other subsidy eligible individual (as defined at § 423.772).

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

§ 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 of this chapter with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

Subpart B—Eligibility and Enrollment.

§ 423.30 Eligibility and enrollment.

(a) *General rule.* (1) An individual is eligible for Part D if he or she:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B; and

(ii) Lives in the service area of a Part D plan, as defined under § 423.4.

(2) Except as provided in paragraphs (b), (c), and (d) of this section, an individual is eligible to enroll in a PDP if:

(i) The individual is eligible for Part D in accordance with paragraph (a)(1) of this section;

(ii) The individual resides in the PDP's service area; and

(iii) The individual is not enrolled in another Part D plan.

(3) Retroactive Part A or Part B determinations. Individuals who become entitled to Medicare Part A or enrolled in Medicare Part B for a retroactive effective date are Part D eligible as of the month in which a notice of entitlement Part A or enrollment in Part B is provided.

(b) *Coordination with MA plans.* A Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan. MA enrollees are not eligible to enroll in a PDP, except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a PACE plan.* A Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under this Part must obtain such coverage through that plan.

(d) *Enrollment in a cost-based HMO or CMP.* A Part D eligible individual enrolled in a cost-based HMO or CMP (as defined under part 417 of this chapter) that elects to receive qualified prescription drug coverage under such plan is ineligible to enroll in another Part D plan. A Part D eligible individual enrolled in a cost-based HMO or CMP offering qualified prescription drug coverage is eligible to enroll in a PDP if the individual does not elect to receive qualified prescription drug coverage under the cost-based HMO or CMP and otherwise meets the requirements of paragraph (a)(2) of this section.

§ 423.32 Enrollment process.

(a) *General rule.* A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate.

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.50.

(i) The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the PDP sponsor. Individuals who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

(ii) Part D eligible individuals enrolling or enrolled in a Part D plan must provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, and consent to the release of the information provided by the individual on other insurance, group health plan or other third-party payment arrangements, as well as any other information on reimbursement of Part D costs collected or obtained from other sources, in a form and manner approved by CMS.

(c) *Timely process an individual's enrollment request.* A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part

D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll or are enrolled in the plan during the periods specified in § 423.38.

(d) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(e) *Maintenance of enrollment.* An individual who is

enrolled in a PDP remains enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP or MA-PD plan;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntary disenrolled from the PDP in accordance with § 423.44(b)(2);

(iv) The PDP is discontinued within the area in which the individual resides; or

(iv) The individual is enrolled after the initial enrollment, in accordance with § 423.34(c).

(f) *Enrollees of cost-based HMOs or CMPs and PACE.* Individuals enrolled in a cost-based HMO or CMP plan (as defined in part 417 of this chapter) or PACE (as defined in § 460.6 of this chapter) that offers prescription drug coverage under this part as of December 31, 2005, remain enrolled in that plan as of January 1, 2006, and receive Part D benefits offered by that plan until one of the conditions in § 423.32(e) are met.

§ 423.34 Enrollment of full-benefit dual eligible individuals.

(a) *General rule.* CMS must ensure the enrollment into Part D plans full-benefit dual eligible individuals who fail to enroll in a Part D plan.

(b) *Definition of full-benefit dual eligible individual.* For purposes of this section, a full-benefit dual eligible individual means an individual who is:

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. ; or

(ii) Medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a).

(c) *Enrolling a full-benefit duel eligible individual.* Notwithstanding § 423.32(e), during the annual coordinated election period, CMS may enroll a full-benefit dual eligible individual in another PDP if CMS determines that the further enrollment is warranted.

(d) *Automatic enrollment rules.* (1) *General rule.* CMS must automatically enroll full-benefit dual eligible individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the individual resides that has a monthly beneficiary premium that does not exceed the low-income premium subsidy amount (as defined in § 423.780(b)). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low-income premium subsidy amount, individuals must be enrolled in such PDPs on a random basis.

(2) Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit. Full-benefit dual eligible individuals enrolled in an MA Private Fee For Service (PFFS) plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in a Part D plan must be automatically enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(e) *Declining enrollment and disenrollment.* Nothing in this section prevents a full-benefit dual eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under § 423.38.

(f) *Effective date of enrollment.* Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual eligible individuals as of December 31, 2005;

(2) The first day of the month the individual is eligible for Part D under § 423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under § 423.30(a)(1) on or after January 1, 2006; and

(3) For individuals who are eligible for Part D under § 423.30(a)(1) and subsequently become newly eligible for Medicaid on or after January 1, 2006, enrollment is effective as soon as practicable after being identified as a newly full-benefit dual eligible individual, in a process to be determined by CMS.

§ 423.36 Disenrollment process.

(a) *General rule.* An individual may disenroll from a PDP during the periods specified in § 423.38 by enrolling in a different PDP plan, submitting a disenrollment request to the PDP in the form and manner prescribed by CMS, or filing the appropriate disenrollment request through other mechanisms as determined by CMS.

(b) *Responsibilities of the PDP sponsor.* The PDP sponsor must—

(1) Submit a disenrollment notice to CMS within timeframes CMS specifies;

(2) Provide the enrollee with a notice of disenrollment as CMS determines and approves; and

(3) File and retain disenrollment requests for the period specified in CMS instructions.

(c) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(1) There never was a legally valid enrollment; or

(2) A valid request for disenrollment was properly made but not processed or acted upon.

§ 423.38 Enrollment periods.

(a) *Initial enrollment period for Part D—Basic rule.* The initial enrollment period is the period during which an individual is first eligible to enroll in a Part D plan.

(1) *In 2005.* An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006, has an initial enrollment period from November 15, 2005 through May 15, 2006.

(2) *February 2006.* An individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006.

(3) *March 2006 and subsequent months.* (i) Except as provided in paragraph (a)(3)(ii) and (a)(3)(iii) of this section, the initial enrollment period for an individual who is first eligible to enroll in a Part D plan on or after March 2006 is the same as the initial enrollment period for Medicare Part B under § 407.14 of this chapter.

(ii) Exception. For those individuals who are not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B, their initial enrollment period under this Part is the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

(iii) An individual who becomes entitled to Medicare Part A or enrolled in Part B for a retroactive effective date has an initial enrollment period under this Part beginning with the month in which notification of the Medicare determination is received and ending on the last day of the third month following the month in which the notification was received.

(b) *Annual coordinated election period.* (1) *For 2006.* This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 and subsequent years.* For coverage beginning 2007 or any subsequent year, the annual coordinated election period is November 15th through December 31st for coverage beginning the following calendar year.

(c) *Special enrollment periods.* A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll in another PDP or MA-PD plan (as provided at § 422.62(b) of this chapter), as applicable, at any time under any of the following circumstances:

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable

coverage as defined under § 423.56(a). Loss of credible prescription drug coverage due to failure to pay any required premium is not considered involuntary loss of the coverage.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage.

(3) The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf.

(4) The individual is a full-benefit dual eligible individual as defined under section 1935(c)(6) of the Act.

(5) The individual elects to disenroll from a MA-PD plan and elects coverage under Medicare Part A and Part B in accordance with § 422.62(c) of this chapter.

(6) The PDP sponsor's contract is terminated by the PDP sponsor or by CMS, as provided under § 423.507 through § 423.510, or the PDP plan is no longer offered in the area when the individual resides.

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered.

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following—

(A) Failure to provide the individual on a timely basis benefits available under the plan;

(B) Failure to provide benefits in accordance with applicable quality standards; or

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(ii) The individual meets other exceptional circumstances as CMS may provide.

§ 423.40 Effective dates.

(a) *Initial enrollment period.* (1) An enrollment made prior to the month of entitlement to Part A or enrollment in Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or enrolled in Part B.

(2) Except as otherwise provided under § 423.34(f), an enrollment made during or after the month of entitlement to Part A or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(3) If the individual is not eligible to enroll in Part D on the first day of the calendar month following the month in which the election to enroll in Part D is made, the enrollment in Part D is effective the first day of the month the individual is eligible for Part D.

(4) In no case is an enrollment in Part D effective before January 1, 2006 or before entitlement to Part A or enrollment Part B.

(b) *Annual coordinated election periods.* (1) *General rule.* Except as provided under paragraph (b)(2) of this section, for an enrollment or change of enrollment in Part D made during an annual coordinated election period as described in § 423.38(b), the coverage or change in coverage is effective as of the first day of the following calendar year.

(2) *Exception for January 1, 2006 through May 15, 2006.* Enrollment elections made during the annual coordinated election period between January 1, 2006 and May 15, 2006 are effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the effective date is determined by CMS, which, to the extent practicable, is determined in a manner consistent with protecting the continuity of health benefits coverage.

§ 423.44 Involuntary disenrollment by the PDP.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, a PDP sponsor may not—

(1) Involuntarily disenroll an individual from any PDP it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment.* (1) *Optional involuntary disenrollment.* A PDP sponsor may disenroll an individual from a PDP it offers in any of the following circumstances:

(i) Any monthly premium is not paid on a timely basis, as specified under paragraph (d)(1) of this section; or

(ii) The individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section.

(2) *Required involuntary disenrollment.* A PDP sponsor must disenroll an individual from a PDP it offers in any of the following circumstances:

(i) The individual no longer resides in the PDP's service area.

(ii) The individual loses eligibility for Part D.

(iii) Death of the individual.

(iv) The PDP sponsor's contract is terminated by CMS

or by a PDP or through mutual consent. The PDP sponsor must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at § 423.507 through § 423.510.

(v) The individual materially misrepresents

information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage.

(c) *Notice requirement.* (1) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(2)(iv) of this section (that is, other than death or loss of Part D eligibility, the PDP sponsor must give the individual timely notice of the disenrollment with an explanation of why the PDP is planning to disenroll the individual.

(2) Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(iii) of this section must—

(i) Be provided to the individual before submission of the disenrollment notice to CMS; and

(ii) Include an explanation of the individual's right to file a grievance under the PDP's grievance procedures.

(d) *Process for disenrollment.* (1) *Monthly PDP premiums that are not paid timely.* A PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

(i) The PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The PDP sponsor gives the enrollee notice of

disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) Reenrollment in the PDP. If an individual is

disenrolled from the PDP for failure to pay monthly PDP premiums, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs until the individual has paid any past premiums due to the PDP sponsor.

(2) *Disruptive behavior.* (i) *Definition.* A PDP enrollee is disruptive if his or her behavior substantially impairs the plans ability to arrange or provide for services to the individual or other plan members. An individual cannot be considered disruptive if the behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* A PDP may disenroll an individual whose behavior is disruptive as defined in § 423.44(d)(2)(i) only after the PDP sponsor meets the requirements described in this section and after CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimers disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures. The individual has a right to submit any information or explanation that he or she may wish to the PDP.

(iv) *Documentation*. The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The PDP sponsor may request from CMS the ability to decline future enrollment by the individual. The PDP sponsor must submit this information and any documentation received by the individual to CMS.

(v) *CMS review of the proposed disenrollment*. CMS reviews the information submitted by the PDP sponsor and any information submitted by the individual (which the PDP sponsor has submitted to CMS) to determine if the PDP sponsor has fulfilled the requirements to request disenrollment for disruptive behavior. If the PDP sponsor has fulfilled the necessary requirements, CMS reviews the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS ensures that staff with appropriate clinical or medical expertise reviews the case before making a final decision. The PDP sponsor is required to provide a reasonable accommodation, as determined by CMS, for the individual in exceptional circumstances that CMS deems necessary. CMS notifies the PDP sponsor within 5 working days after making its decision.

(vi) *Exception for fallback prescription drug plans*. CMS reserves the right to deny a request from a fallback prescription drug plan as defined in § 423.855 to disenroll an individual for disruptive behavior.

(vii) *Effective date of disenrollment*. If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(3) *Loss of Part D eligiblity*. If an individual is no longer eligible for Part D, CMS notifies the PDP that the disenrollment is effective the first day of the calendar month following the last month of Part D eligibility.

(4) *Death of the individual*. If the individual dies, disenrollment is effective the first day of the calendar month following the month of death.

(5) *Individual no longer resides in the PDP service area—Basis for disenrollment*. The PDP must disenroll an individual if the individual notifies the PDP that he or she has permanently moved out of the PDP service area.

(6) *Plan termination*. (i) When a PDP contract terminates as provided in § 423.507 through § 423.510, the PDP sponsor must give each affected PDP enrollee notice of the effective date of the plan termination and a description of alternatives for obtaining prescription drug coverage under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(7) *Misrepresentation of third-party reimbursement*.

(i) If CMS determines an individual has materially misrepresented information to the PDP sponsor as described under § 423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP sponsor gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP*. Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

§ 423.46 Late enrollment penalty.

(a) *General*. A Part D eligible individual must pay the late penalty described under § 423.286(d)(3) if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

(1) The individual was eligible to enroll in a Part D plan;

(2) The individual was not covered under any creditable prescription drug coverage; and

(3) The individual was not enrolled in a Part D plan.

(b) [Reserved]

§ 423.48 Information about Part D.

Each Part D plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

§ 423.50 Approval of marketing materials and enrollment forms.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) and (a)(3) of this section, a Part D plan may not distribute any marketing materials (as defined in paragraph (b) of this section), or enrollment forms, or make such materials or forms available to Part D eligible individuals, unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in paragraph (c) of this section; and

(ii) CMS does not disapprove the distribution of the material or form.

(2) If the Part D sponsor is deemed by CMS to meet certain performance requirements established by CMS, the Part D sponsor may distribute designated marketing materials 5 days following their submission to CMS.

(3) Prior to distribution, the Part D sponsor submits and certifies that for certain types of marketing materials it followed all applicable marketing guidelines, or for certain other marketing materials that it used, without modification, proposed model language as specified by CMS.

(b) *Definition of marketing materials.* Marketing materials include any informational materials targeted to Medicare beneficiaries which—

(1) Promote the Part D plan.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.

(3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.

(c) *Examples of marketing materials.* Examples of marketing materials include, but are not limited to—

(1) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(2) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(3) Presentation materials such as slides and charts.

(4) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(5) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(6) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(7) Membership or claims processing activities.

(d) *Guidelines for CMS review.* In reviewing marketing material or enrollment forms under paragraph (a) of this section, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(1) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling—

(i) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(ii) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(iii) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(3) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(4) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(e) *Deemed approval.* If CMS has not disapproved the distribution of a marketing materials or form submitted by a Part D sponsor for a Part D plan in a Part D region, CMS is deemed to not have disapproved the distribution of the marketing material or form in all other Part D regions covered by the Part D plan, with the exception of any portion of the material or form that is specific to the Part D region.

(f) *Standards for Part D marketing.* (1) In conducting

marketing activities, a Part D plan may not—

(i) Provide for cash or other remuneration as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the Part D plan.

(ii) Engage in any discriminatory activity such as, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

(v) Use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors.

(vi) Accept Part D plan enrollment forms in provider offices, pharmacies or other places where health care is delivered.

(vii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(viii) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(2) In its marketing, the Part D organization must—

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition.* Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with CMS actuarial guidelines.

(b) *Types of coverage.* The following coverage is considered creditable if it meets the definition provided in paragraph (a) of this section:

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act.

(4) Coverage under State Pharmaceutical

Assistance Programs (SPAP) as defined at § 423.454.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 423.205.

(7) Military coverage under chapter 55 of title 10,

U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(10) Coverage provided by a PACE organization.

(11) Coverage provided by a cost-based HMO or CMP under part 417 of this chapter.

(12) Coverage provided through a State High-Risk Pool as defined under 42 CFR 146.113(a)(1)(vii).

(13) Other coverage as the Secretary may determine appropriate.

(c) *General disclosure requirements.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, each entity that offers prescription drug coverage under any of the types described in § 423.56(b), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in the coverage whether the coverage is creditable prescription drug coverage.

(d) *Disclosure of non-creditable coverage.* In the case that the coverage of the type described in § 423.56(b) is not creditable prescription drug, the disclosure described in paragraph (c) of this section to Part D eligible individuals must also include:

(1) The fact that the coverage is not creditable prescription drug coverage, as provided by CMS;

(2) That there are limitations on the periods in a year in which the individual may enroll in Part D plans; and

(3) That the individual may be subject to a late enrollment penalty, as described under § 423.46.

(e) *Disclosure to CMS.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, all other entities listed under paragraph (b) of this section must disclose whether the coverage they provide is creditable prescription drug coverage to CMS in a form and manner described by CMS.

(f) *Notification content and timing requirements.* The disclosure notification to Part-D eligible individuals required in § 423.56(c) and (d) must be provided in a form and manner prescribed by CMS. Notices must be provided, at minimum, at the following times:

(1) Prior to an individual's initial enrollment period for Part D, as described under § 423.38(a);

(2) Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;

(3) Prior to the commencement of the Annual Coordinated Election Period that begins on November 15 of each year, as defined in § 423.38(b); and

(4) Upon request by the individual.

(g) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, the individual may apply to CMS to have the coverage treated as creditable prescription drug coverage for purposes of applying the late penalty described in § 423.46.

Subpart C—Benefits and Beneficiary Protections

§ 423.100 Definitions.

As used in this part, unless otherwise specified-

Actual cost means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).

Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing.

Alternative prescription drug coverage means coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of § 423.104(e). The term alternative prescription drug coverage must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(f)(1)).

Basic prescription drug coverage means coverage of Part D drugs that is either standard prescription drug coverage or basic alternative coverage.

Bioequivalent has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Contracted pharmacy network means pharmacies, including retail, mail-order, and institutional pharmacies, under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

Covered Part D drug means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under § 423.566, § 423.580, and § 423.600, § 423.610, § 423,620, and § 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124.

Dispensing fees means costs that-

(1) Are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed;

(2) Include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy. In the case of pharmacies owned and operated by a Part D plan itself, notwithstanding number (3) of this definition, dispensing fees are understood to be the equivalent of all reasonable costs discussed in the previous sentence, including the salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and equipment necessary to operate the pharmacy; and

(3) Do not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including systems costs for interfacing with pharmacies.

Government-funded health program means any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including any of the following:

(1) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meets the requirements of section 2103 of the Act;

(2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act;

(3) The veterans' health care program under Chapter 17 of title 38 of the United States Code;

(4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and

(5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

Group health plan, for purposes of applying the definition of incurred costs in §423.100, has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle, as used in this subpart.

Incurred costs means costs incurred by a Part D enrollee for covered Part D drugs—

(1) That are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under §423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under §423.124(b); and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under a State Pharmaceutical Assistance Program (as defined in §423.454); or

(iii) Under §423.782.

Insurance means a health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following:

(1) Health insurance coverage (as defined in 42 U.S.C. 300gg–91(b)(1));

(2) A Medicare Advantage plan (as described under section 1851(a)(2) of the Act); and

(3) A PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act)

but specifically excluding a personal health savings vehicle.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy means a long-term care pharmacy that is a network pharmacy.

Negotiated prices means prices for covered Part D drugs that-

(1) Are available to beneficiaries at the point of sale at network pharmacies;

(2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and

(3) Includes any dispensing fees.

Network pharmacy means a licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

Non-preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

Or otherwise means through a government-funded health program.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Part D drug means—

(1) Unless excluded under number (2) of this definition, any of the following

if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;

(iii) Insulin described in section 1927(k)(2)(C) of the Act;

(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze; or

(v) A vaccine licensed under section 351 of the Public Health Service Act.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Person means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Personal health savings vehicle means a vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax-free basis including any of the following—

(1) A Health Savings Account (as defined under section 220 of the Internal Revenue Code);

(2) A Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and

(3) An Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code);

but specifically excluding a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002–41 and Internal Revenue Notice 2002–45)

Plan allowance means the amount Part D plans that offer coverage other than defined standard coverage may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of § 423.124(b).

Preferred drug means a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D plan.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage

Retail pharmacy means any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

Required prescription drug coverage means coverage of Part D drugs under an MA-PD plan that consists of either—

(1) Basic prescription drug coverage; or

(2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium (as defined under section 1854(b)(2)(C) of the Act) applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of Part D drugs that meets the requirements of § 423.104(d). The term standard prescription drug coverage must be either—

(1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(A) and (d)(5)(i)); or

(2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(B) or cost-sharing as described in § 423.104(d)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits that meet the requirements of § 423.104(f)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations.''

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means the price that an out-of-network pharmacy or a physician's office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.

§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General*. Subject to the conditions and limitations set forth in this subpart, a Part D sponsor must provide enrollees with coverage of the benefits described in paragraph (c) of this section. The benefits may be provided directly by the Part D sponsor or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of prescription drug plans*. A PDP sponsor offering a prescription drug plan must offer that plan to all Part D eligible beneficiaries residing in the plan's service area.

(c) *Types of benefits*. The coverage provided by a Part D plan must be qualified prescription drug coverage.

(d) *Standard prescription drug coverage*. Standard prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements

(1) *Deductible*. An annual deductible equal to—

(i) *For 2006*. $250; or

(ii) *For years subsequent to 2006*. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $5.

(2) *Cost-sharing under the initial coverage limit*.

(i) *25 Percent coinsurance*. Coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and up to the initial coverage limit under paragraph (d)(3) of this section, that is—

(A) Equal to 25 percent of actual cost; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent of actual cost, as determined through processes and methods established under § 423.265(c) and (d).

(ii) *Tiered copayments*. A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraph (d)(2)(i)(B) of this section and are approved as described in § 423.272(b)(2).

(3) *Initial coverage limit*. The initial coverage limit is equal to—

(i) *For 2006*. $2,250.

(ii) *For years subsequent to 2006*. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $10.

(4) *Cost-sharing between the initial coverage limit and the annual out-of-pocket threshold*. Coinsurance for costs for covered Part D drugs above the initial coverage limit described in paragraph (d)(3) of this section and annual out-of-

pocket threshold described in paragraph (d)(5)(iii) of this section that is equal to 100 percent of actual costs.

(5) *Protection against high out-of-pocket expenditures.* (i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section, cost-sharing equal to the greater of—

(A) *Copayments.* (1) In 2006, $2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug; and

(2) For subsequent years, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

(B) *Coinsurance.* Coinsurance of five percent of actual cost.

(ii) As determined through processes and methods established under § 423.265(c) and (d), a Part D plan may substitute for cost-sharing under paragraph (d)(5)(i) of this section an amount that is actuarially equivalent to expected cost-sharing under paragraph (d)(5)(i) of this section.

(iii) *Annual out-of-pocket threshold.* For purposes of this part, the annual out-of-pocket threshold equals—

(A) *For 2006.* $3,600.

(B) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $50.

(iv) *Annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(e) *Alternative prescription drug coverage.* Alternative prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements—

(1) Has an annual deductible that does not exceed the annual deductible specified in paragraph (d)(1) of this section;

(2) Imposes cost-sharing no greater than that specified in paragraphs (d)(5)(i) or (ii) of this section once the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section is met;

(3) Has a total or gross value that is at least equal to the total or gross value of defined standard coverage.

(4) Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under § 423.782 for the coverage; and

(5) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, for costs incurred for covered Part D drugs, that are equal to the initial coverage limit under paragraph (d)(3) of this section, of an amount equal to at least the product of -

(i) The amount by which the initial coverage limit described in paragraph (d)(3) of this section for the year exceeds the deductible described in paragraph (d)(1) of this section; and

(ii) 100 percent minus the coinsurance percentage specified in paragraph (d)(2)(i) of this section.

(f) *Enhanced alternative coverage.* (1) Enhanced alternative coverage must meet the requirements under paragraph (e) of this section and includes-

(i) Basic prescription drug coverage, as defined in § 423.100; and

(ii) Supplemental benefits, which include-

(A) Coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100; or

(B) Any of the following changes or combination of changes that increase the actuarial value of benefits under the Part D plan above the actuarial value of defined standard prescription drug coverage, as determined through processes and methods established under § 423.265—

(*1*) A reduction in the annual deductible described in paragraph (d)(1) of this section;

(*2*) A reduction in the cost-sharing described in paragraphs (d)(2) or (d)(5) of this section, or

(*3*) An increase in the initial coverage limit described in paragraph (d)(3) of this section.

(C) Both the coverage described in paragraph (f)(1)(ii)(A) of this section and the changes or combination of changes described in paragraph (f)(1)(ii)(B) of this section.

(2) *Restrictions on the offering of enhanced alternative coverage by PDP sponsors.* A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

(3) *Restrictions on the offering of enhanced alternative coverage by MA organizations.* Effective January 1, 2006, an MA organization—

(i) May not offer an MA coordinated care plan, as defined in § 422.4 of this chapter, in an area unless either that plan (or another MA plan offered by the MA organization in that same service area) includes required prescription drug coverage; and

(ii) May not offer prescription drug coverage (other than that required under Parts A and B of title XVIII of the Act) to an enrollee—

(A) Under an MSA plan, as defined in § 422.2 of this chapter; or

(B) Under another MA plan (including a private fee-for-service plan, as defined in § 422.4 of this chapter) unless the drug coverage under the other plan provides qualified prescription drug coverage and unless the requirements of paragraph (f)(3)(i) of this section are met.

(4) *Restrictions on the offering of enhanced alternative coverage by cost plans.*

(i) A cost plan that elects to offer qualified prescription drug coverage may offer enhanced alternative coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter only if the cost plan also offers basic prescription drug coverage. An enrollee in the cost plan may, at the individual's option, elect whether to receive qualified prescription drug coverage under the cost plan and, if so, whether to receive basic prescription drug coverage or, if offered by the cost plan, enhanced alternative coverage.

(ii) A cost plan that offers qualified prescription drug coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter may not offer prescription drug coverage that is not qualified prescription drug coverage. A cost plan that does not offer qualified prescription drug coverage under § 417.440(b)(2)(ii) of this chapter may offer prescription drug coverage that is not qualified prescription drug coverage under § 417.440(b)(2)(i) of this chapter.

(g) *Negotiated prices.* (1) *Access to negotiated prices.* A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit.

(2) *Interaction with Medicaid best price.* Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs by the following entities are not taken into account in establishing Medicaid's best price under section 1927(c)(1)(C) of the Act—

(i) A Part D plan, as defined in § 423.4; or

(iii) A qualified retiree prescription drug plan (as defined in § 423.882) for Part D eligible individuals.

(3) *Disclosure.* (i) A Part D sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in § 423.782, or in the form of lower monthly beneficiary premiums or lower covered Part D drug prices at the point of sale.

(ii) Information on negotiated prices disclosed to CMS under paragraph (g)(3) of this section is protected under the confidentiality provisions applicable under section 1927(b)(3)(D) of the Act.

(4) *Audits*. CMS and the Office of the Inspector General may conduct periodic audits of the financial statements and all records of Part D sponsors pertaining to any qualified prescription drug coverage they may offer under a Part D plan.

§ 423.112 Establishment of prescription drug plan service areas.

(a) *Service area for prescription drug plans*. The service area for a prescription drug plan other than a fallback prescription drug plan consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

(b) *Establishment of PDP regions*. (1) *General*. CMS establishes PDP regions in a manner consistent with the requirements for the establishment of MA regions as described at § 422.455 of this chapter.

(2) *Relation to MA regions*. To the extent practicable, PDP regions are the same as MA regions. CMS may establish PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories*. CMS establishes a PDP region or regions for States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions*. CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan*. Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access*. (1) *Standards for convenient access to network pharmacies*. Except as provided in paragraph (a)(7) of this section, a Part D plan must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that for beneficiaries residing in each State in a prescription drug plan's service area(as defined in § 423.112(a)), each State in a regional MA-PD plan's service area (as defined in § 422.2 and § 422.455(a) of this chapter), a local MA-PD plan's service area (as defined in § 422.2 of this chapter), or a cost plan's geographic area (as defined in § 417.401 of this chapter), the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D plan live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D plan live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D plan live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access*. Part D plans may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies*. A Part D plan's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies*. A Part D plan's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions.

(5) *Access to long-term care pharmacies.* A Part D plan must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The plan must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D plan must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The plan must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of—

(i) An MA-PD plan or cost plan (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost plan, provided the organization's or plan's pharmacy network meets the access standard set forth under § 422.112 of this chapter for an MA plan, or § 417.416(e) of this chapter for a cost plan.

(ii) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D plan's standard terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D plan's contracted pharmacy network.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) *Formulary requirements.* A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to-

(A) The Part D sponsor and Part D plan; and

(B) Pharmaceutical manufacturers.

(iii) Includes at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(iv) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(v) Considers whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

(vi) Reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.

(vii) Evaluates and analyzes treatment protocols and procedures related to the plan's formulary at least annually consistent with written policy guidelines and other CMS instructions.

(viii) Documents in writing its decisions regarding formulary development and revision and utilization management activities.

(ix) Meets other requirements consistent with written policy guidelines and other CMS instructions.

(2) Provision of an adequate benefit. A Part D plan's formulary must-

(i) Except as provided in paragraph (b)(2)(ii) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug.

(ii) Include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, the following-

(A) That only two drugs are available in that category or class of Part D drugs; and

(B) That one drug is clinically superior to the other drug in that category or class of Part D drugs.

(iii) Include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.

(iv) Be approved by CMS consistent with § 423.272(b)(2).

(3) *Transition Process.* A Part D sponsor must provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its Part D plan's formulary. The transition policy must meet requirements consistent with written policy guidelines and other CMS instructions.

(4) *Limitation on changes in therapeutic classification.* Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year.

(5) *Provision of notice regarding formulary changes*

(i) Prior to removing a covered Part D drug from its Part D plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective, and must either—

(A) Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or

(B) At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change.

(ii) The written notice must contain the following information-

(A) The name of the affected covered Part D drug;

(B) Whether the plan is removing the covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(C) The reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(D) Alternative drugs in the same therapeutic category or class or cost-

sharing tier and expected cost-sharing for those drugs; and

(E) The means by which enrollees may obtain a coverage determination under § 423.566 or exception under § 423.578.

(iii) Part D sponsors may immediately remove from their Part D plan formularies covered Part D drugs deemed unsafe by the Food and Drug Administration or removed from the market by their manufacturer without meeting the requirements of paragraphs (b)(5)((i) of this section. Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists consistent with the requirements of paragraphs (b)(5)(ii)(A), (b)(5)(ii)(B), (b)(5)(ii)(C), and (b)(5)(ii)(D) of this section.

(6) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided under paragraph (b)(5)(iii) of this section, a Part D sponsor may not remove a covered Part D drug from its Part D plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its plan's formulary, between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(7) *Provider and patient education.* A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary.

(c) *Use of standardized technology.* A Part D sponsor must issue and reissue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs as provided under § 423.104(g). The card or other technology must comply with standards CMS establishes.

§ 423.124 Special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies.

(a) *Out-of-network access to covered part D drugs.* (1) Out-of-network pharmacy access. A Part D sponsor must ensure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when the enrollees—

(i) Cannot reasonably be expected to obtain such drugs at a network pharmacy; and

(ii) Do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

(2) Physician's office access. A Part D sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office.

(b) *Financial responsibility for out-of-network access to covered Part D drugs.* A Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs as provided in paragraph (a) of this section to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance, consistent with the requirements of § 423.104(d)(2)(i)(B) and § 423.104(e).

(c) *Limits on out-of-network access to covered Part D.* A Part D sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

§ 423.128 Dissemination of Part D plan information.

(a) *Detailed description.* A Part D sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of Part D plan description.* The Part D plan description must include the following information about the qualified prescription drug coverage offered under the Part D plan—

(1) *Service area.* The plan's service area.

(2) *Benefits.* The benefits offered under the plan, including-

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments,

deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) *Cost-sharing.* A description of how a Part D eligible individual may obtain more information on cost-sharing requirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.

(4) *Formulary.* Information about the plan's formulary, including-

(i) A list of drugs included on the plan's formulary;

(ii) The manner in which the formulary (including any tiered formulary structure and utilization management procedures used) functions;

(iii) The process for obtaining an exception to a plan's formulary or tiered cost-sharing structure; and

(iv) A description of how a Part D eligible individual may obtain additional information on the formulary, in accordance with paragraph (d) of this section.

(5) *Access.* The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the Part D sponsor meets the requirements of § 423.120(a)(1) for access to covered Part D drugs;

(6) *Out-of-network coverage.* Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with § 423.124(a).

(7) *Grievance, coverage determinations, and appeals procedures.* All grievance, reconsideration, exceptions, coverage determination, reconsideration, exceptions, and appeal rights and procedures required under § 423.564 et. seq.

(8) *Quality assurance policies and procedures.* A description of the quality assurance policies and procedures required under § 423.153(c), as well as the medication therapy management program required under § 423.153(d).

(9) *Disenrollment rights and responsibilities.*

(10) Potential for contract termination. The fact that a Part D sponsor may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in a Part D plan;

(c) *Disclosure upon request of general coverage information, utilization, and grievance information.* Upon request of a Part D eligible individual, a Part D sponsor must provide the following information—

(1) *General coverage information.* General coverage information, including—

(i) *Enrollment procedures.* Information and instructions on how to exercise election options under this part;

(ii) *Rights.* A general description of procedural rights (including grievance, coverage determination, reconsideration, exceptions, and appeals procedures) under this part;

(iii) *Benefits.* (A) Covered services under the Part D plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the Part D plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) The Part D plan's out-of-network pharmacy access policy.

(iv) Premiums;

(v) The Part D plan's formulary;

(vi) The Part D plan's service area; and

(vii) Quality and performance indicators for benefits under the Part D plan as determined by CMS.

(2) The procedures the Part D sponsor uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 423.564;

(ii) Appeals according to § 423.580 et. seq.; and

(iii) Exceptions according to § 423.578.

(4) Financial condition of the Part D sponsor, including the most recently audited information regarding, at a minimum, a description of the financial condition of the Part D sponsor offering the Part D plan.

(d) *Provision of specific information.* Each Part D sponsor offering qualified prescription drug coverage under a Part D plan must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(2) An Internet website that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its Part D plan, updated at least monthly.

(iii) Provides current and prospective Part D enrollees with at least 60 days notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary.

(3) The provision of information in writing, upon request.

(e) *Claims information.* A Part D sponsor must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) Include any applicable formulary changes for which Part D plans are required to provide notice as described in § 423.120(b)(5).

(6) Be provided during any month when prescription drug benefits are provided under this part, including for covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements.* Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in the case of—

(1) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy;

(3) An I/T/U network pharmacy;

(4) A network pharmacy that is located in any of the U.S. territories; and

(5) Other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section as follows—

(1) For long-term care network pharmacies, which must meet the requirement in paragraph (a) of this section by providing such information to Part D plans for inclusion in the written explanations of benefits required under § 423.128(e); and

(2) Under other circumstances where CMS deems compliance with the requirement under paragraph (b) of this section to be impossible or impracticable.

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, a PDP sponsor must establish procedures to do the following—

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The PDP sponsor must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information is used within the organization; and

(2) To whom and for what purposes it discloses the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or under court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

Subpart D—Cost Control and Quality Improvement Requirements for Part D Plans

§ 423.150 Scope.

This subpart sets forth the requirements relating to the following:

(a) Drug utilization management programs, quality assurance measures and systems, and medication therapy management programs (MTMP) for Part D sponsors.

(b) Consumer satisfaction surveys of Part D plans.

(c) Electronic prescription program.

(d) Quality improvement organization (QIO) activities.

(e) Compliance deemed on the basis of accreditation.

(f) Accreditation organizations.

(g) Procedures for the approval of accreditation

organizations as a basis for deeming compliance.

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

(a) *General rule.* Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTMP as described in paragraphs (b), (c), and (d) of this section.

(b) *Drug utilization management.* A Part D sponsor must have established a reasonable and appropriate drug utilization management program that—

(1) Includes incentives to reduce costs when medically appropriate;

(2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications; and

(3) Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

(c) *Quality assurance.* A Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use that include all of the following—

(1) Representation that network providers are required to comply with minimum standards for pharmacy practice as established by the States.

(2) Concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution. The review must include, but not be limited to,

(i) Screening for potential drug therapy problems due to therapeutic duplication.

(ii) Age/gender-related contraindications.

(iii) Over-utilization and under-utilization.

(iv) Drug-drug interactions.

(v) Incorrect drug dosage or duration of drug therapy. (vi) Drug-allergy contraindications.

(vii) Clinical abuse/misuse.

(3) Retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in a sponsor's Part D plan, or associated with specific drugs or groups of drugs.

(4) Internal medication error identification and reduction systems.

(5) Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.

(d) *Medication therapy management program (MTMP).*

(1) *General rule.* A Part D sponsor must have established a MTMP that—

(i) Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries described in paragraph (d)(2) of this section;

(iii) May be furnished by a pharmacist or other qualified provider; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who—

(i) Have multiple chronic diseases;

(ii) Are taking multiple Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program (CCIP) under section 1807 of the Act. A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.

(5) *Considerations in pharmacy fees.* An applicant to become a Part D sponsor must—

(i) Describe in its application how it takes into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(6) *MTMP reporting.* A Part D sponsor must provide CMS with information regarding the procedures and performance of its MTMP, according to guidelines specified by CMS.

(e) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in § 422.4(a)(3) of this chapter providing qualified prescription drug coverage, the requirements under paragraphs (b) and (d) of this section do not apply.

§ 423.156 Consumer satisfaction surveys.

CMS conducts consumer satisfaction surveys of Part D plan enrollees similar to the surveys it conducts of MA enrollees under § 422.152 (b) of this chapter.

§ 423.159 Electronic prescription program.

(a) [Reserved]

(b) [Reserved]

(c) *Requirement.* Part D sponsors must support and comply with electronic prescription standards relating to covered Part D drugs for Part D enrollees developed by CMS once final standards are effective.

(d) *Promotion of electronic prescribing by MA-PD plans.* An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including initial standards and final standards established by CMS once final standards are effective. Any payments must be in compliance with applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act) and the Federal anti kickback statute (section 1128B(b) of the Act).

§ 423.162 Quality improvement organization activities.

(a) *General rule.* Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of part 480 of this chapter. Part D sponsors are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *Applicability of QIO confidentiality provisions.* The provisions of part 480 of this chapter apply to Part D sponsors in the same manner as such provisions apply to institutions under part 480 of this chapter.

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A Part D sponsor is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The Part D sponsor is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS for the purposes of assessing the Part D sponsor's compliance with Medicare requirements.

(b) Deemable requirements. The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under § 423.120 and § 423.124.

(2) Drug utilization management programs, quality assurance measures and systems, and MTMPs as provided under § 423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.

(4) A program to protect against fraud, waste and abuse, as described in § 423.504(b)(4)(vi)(H).

(c) *Effective date of deemed status.* The date the Part D sponsor is deemed to meet the applicable requirements is the later of the following:

(1) The date the accreditation organization is approved by CMS.

(2) The date the Part D sponsor is accredited by the accreditation organization.

(d) *Obligations of deemed Part D sponsors.* A Part D sponsor deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of a Part D sponsor's deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the Part D sponsor does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the Part D sponsor.

(3) The Part D sponsor fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* CMS retains the authority to initiate enforcement action against any Part D sponsor that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

§ 423.168 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization for a given standard under this part if the organization meets the following conditions:

(1) In accrediting Part D sponsors and Part D plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, Part D sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment.* (1) *Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice-

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS uses in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final notice in the FEDERAL REGISTER indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed Part D sponsors.

(iv) Information about any Part D sponsor against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the Part D sponsor's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited Part D sponsor, a deficiency that as determined by the accrediting organization poses immediate jeopardy to the plan's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited Part D sponsors.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, regardless of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to the following:

(i) Reviewing documents.

(ii) Auditing meetings concerning the accreditation process.

(iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming, based on accreditation, no longer guarantees that the Part D sponsor meets the requirements for offering qualified prescription drug coverage, and failure to meet those requirements may jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 423.165 or § 423.171.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

§ 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials (when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS):

(1) The types of Part D plans and sponsors that it reviews as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including the following:

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited Part D sponsors of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including the—

(i) Size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) Education and experience requirements surveyors must meet;

(iii) Content and frequency of the in-service training provided to survey personnel;

(iv) Evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Organization's policies and practice for the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited Part D sponsors and MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval also must submit the following supporting documentation—

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that it's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 423.168(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval is granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received a notice of denial of its request for approval may request a reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based.

(ii) Can demonstrate that the Part D sponsors that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS' denial of its request for approval may not submit a new request until the reconsideration is administratively final.

Subpart E [Reserved]

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

§ 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

§ 423.258 Definitions.

For the purposes of this subpart, the following definitions apply:

Full risk plan means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

Limited risk plan means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

Standardized bid amount means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA-PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

§ 423.265 Submission of bids and related information.

(a) *Eligibility for bidding*. An applicant may submit a bid to become a Part D plan sponsor.

(b) *Bid submission*. Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(c) *Basic rule for bid*. Each potential Part D sponsor must submit a bid and supplemental information in a format to be specified by CMS for each Part D plan it offers. Each bid must reflect a uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1).

(1) *Included costs*. The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs*. The bid does not include costs associated with payments by the enrollee for deductible, co-payments, coinsurance, and liability above the plan allowance in the case of out-of-network claims, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation*. The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids.

(d) *Specific requirements for bids*. The bid and supplemental information submission must include the following information:

(1) *Coverage*. A description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing.

(2) *Actuarial value of bid components*. The applicant must provide the following information on bid components, as well as actuarial certification that the values are calculated according to CMS guidelines on actuarial valuation, including adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard prescription drug coverage) has on drug utilization, if applicable.

(i) The actuarial value of the qualified prescription drug coverage to be offered under each plan for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1) and the basis for the estimate.

(ii) The portion of the bid attributable to basic prescription drug coverage and the portion (if any) attributable to supplemental benefits.

(iii) The assumptions regarding reinsurance amounts payable under § 423.329(c) used in calculating the bid.

(iv) The assumptions regarding low-income cost-sharing payable under § 423.329(d) used in calculating the bid.

(v) The amount of administrative costs and return on investment or profit included in the bid.

(3) *Service area*. A description of the service area of the plan.

(4) *Level of risk assumed*. For a potential Part D sponsor, the level of risk assumed in the bid specified in paragraph (e) of this section.

(5) *Plan Average Risk Score*. An estimate of the plan's average prescription drug risk score (as established under § 423.329(b)) for all projected enrollees

for purposes of risk adjusting any supplemental premium.

(6) *Additional information.* Additional information CMS requests to support bid amounts and facilitate negotiation.

(e) *Special rule for PDP sponsors.* Bids for all plans offered by a potential PDP sponsor in a region, but not those of potential MA organizations offering MA-PD plans, PACE organizations offering PACE plans including qualified prescription drug coverage, and cost-based HMOs or CMPs offering section 1876 cost plans including qualified prescription drug coverage, may include a uniform modification of the amount of risk assumed (based on a process to be specified) as described in one or more of the following paragraphs. Any such modification applies to all plans offered by the PDP sponsor in a PDP region.

(1) *Increase in Federal percentage assumed in initial risk corridor.* An equal percentage point increase in the percents applied for costs between the first and second threshold limits under § 423.336(b)(2)(i) and (b)(2)(ii)(A) and § 423.336 (b)(3)(i) and (b)(3)(ii)(A). This provision does not affect the application of a higher percentage for plans in 2006 or 2007 under § 423.336(b)(2)(iii).

(2) *Increase in Federal percentage assumed in second risk corridor.* An equal percentage point increase in the percents applied for costs above the second threshold upper limit or below the second threshold upper limit under paragraphs § 423.336(b)(2)(ii)(B) and (b)(3)(ii)(B).

(3) *Decrease in size of risk corridors.* A decrease in the size of the risk corridors by means of reductions in the threshold risk percentages specified in § 423.336(a)(2)(ii)(A) and/or (a)(2)(ii)(B).

(f) *Special rule for fallback prescription drug plans.* Fallback prescription drug plan bids are not subject to the rules in this section. They must follow requirements specified in § 423.863.

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

(a) *Review and negotiation regarding information, terms and conditions.* CMS reviews the information filed under § 423.265(c) in order to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan. In addition to its general negotiating authority under section 1860D–11(d)(2)(A) of the Act, CMS has authority similar to that of the Director of the Office of Personnel Management for health benefit plans under Chapter 89 of title 5, U.S.C.

(b) *Approval of proposed plans.* CMS approves the Part D plan only if the plan and the Part D sponsor offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

(1) *Application of revenue requirements standard.* CMS approves a bid submitted under § 423.265 only if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section § 423.329(c).

(2) *Plan design.* (i) CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.

(ii) If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, the formulary categories and classes alone will not be found to discourage enrollment.

(iii) A plan that adopts the categories and classes discussed in paragraph (b)(2)(ii) of this section may nevertheless be found to discourage enrollment because it excludes specific drugs from the formulary.

(c) *Limited risk plans.* (1) Application of limited risk plans. There is no limit on the number of full risk plans that CMS approves under paragraph (b) of this section. CMS approves a limited

risk plan in accordance with paragraphs (c)(2) and (c)(3) of this section only if the access requirements under § 423.859 are not otherwise met for a PDP region.

(2) *Maximizing assumption of risk.* CMS gives priority in approval for those limited risk plans bearing the highest level of risk, but may take into account the level of the bids submitted by the plans and is not required to accept the limited risk plan with the highest assumption of risk. In no case does CMS approve a limited risk plan under which the modification of risk level provides for no (or a minimal) level of financial risk.

(3) *Limited exercise of authority.* CMS approves only the minimum number of limited risk plans needed to meet the access requirements.

(d) *Special rules for private fee-for-service (PFFS) plans that offer prescription drug coverage.* PFFS plans (as defined at § 422.4(a)(3)) choosing to offer prescription drug coverage are subject to all MA-PD bid submission and approval requirements applicable to MA-PD plans with the following exceptions:

(1) *Exemption from negotiations.* These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements of § 423.104(h).

(3) *Modification of pharmacy access standard and disclosure requirement.* If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are network pharmacies, § 423.120(a) and § 423.132 requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs does not apply to the plan.

(e) *Special rule for plans with standardized bids sufficiently below the national average monthly bid to result in a negative premium.* In the event of a negative premium, as described in § 423.286(d)(1), CMS negotiates the incorporation of the negative premium amount into the bid as either a reduction in the supplemental premium if the Part D plan already submitted a bid with an enhanced alternative benefit, or CMS requires the addition of new enhanced alternative benefit of no less value than the amount of the negative premium.

§ 423.279 National average monthly bid amount.

(a) Bids included. For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids submitted under § 423.265 in order to calculate the base beneficiary premium, as provided in § 423.286(c). The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each prescription drug plan (not including fallbacks) and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. The calculation does not include bids submitted by MSA plans, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(b) Calculation of weighted average. (1) The national average monthly bid amount is a weighted average, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in a reference month in all Part D plans except MSA plans, fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(2) For purposes of calculating the monthly national average monthly bid amount for 2006, CMS assigns equal weighting to PDP sponsors (other than fallback entities) and assigns MA-PD plans included in the national average bid a weight based on prior enrollment (new MA-PD plans are assigned zero weight).

(c) Geographic adjustment. (1) Upon the development of an appropriate methodology, the national average monthly bid amount for Part D plans will be adjusted to take into account differences in prices for Part D drugs among PDP regions.

(2) CMS does not apply any geographic adjustments if CMS determines that price variations among PDP regions are negligible.

(3) CMS applies any geographic adjustment in a budget neutral manner so as to not result in a change in the aggregate payments that may have been made if CMS had not applied an adjustment.

(4) CMS does not apply any geographic adjustment until an appropriate methodology is developed.

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3) and (e) of this section, and with regard to employer group waivers, the monthly beneficiary premium for a Part D plan in a PDP region is the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium for a Part D plan is the base beneficiary premium, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

(b) *Beneficiary premium percentage.* The beneficiary premium percentage for any year is a fraction, the—

(1) Numerator of which is 25.5 percent; and

(2) Denominator of which is as follows:

(i) 100 percent minus the percentage established in paragraph (b)(2)(ii) of this section.

(ii) The percentage established in this paragraph equals:

(A) The total reinsurance payments that CMS estimates will be paid under § 423.329(c) for the coverage year; divided by—

(B) The amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(c) *Base beneficiary premium.* The base beneficiary premium for a Part D plan for a month is equal to the product of the—

(1) Beneficiary premium percentage as specified in paragraph (b) of this section; and

(2) National average monthly bid amount (computed under § 423.279) for the month.

(d) *Adjustments to base beneficiary premium.* The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable.

(1) *Adjustment to reflect difference between bid and national average bid.* If the amount of the standardized bid amount exceeds the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount, the monthly base beneficiary premium is decreased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount by an amount greater than the base beneficiary premium and results in a negative premium, then the beneficiary premium is zero, and the excess amount is applied to supplemental Part D benefits as described in § 423.272(e).

(2) *Increase for supplemental prescription drug benefits.* The portion of the Part D plan approved bid that is attributable to supplemental prescription drug benefits increases the beneficiary premium. This supplemental portion of the bid may be adjusted to reflect the average risk of enrollees in the plan as determined based on negotiations between CMS and the Part D sponsor offering the plan.

(3) *Increase for late enrollment penalty.* The base beneficiary premium for a Part D enrollee subject to the late enrollment penalty is increased by the amount of any late enrollment penalty.

(i) *Late enrollment penalty amount.* The penalty amount for a Part D eligible individual for a continuous period of eligibility (as provided in § 423.46(a)) is the greater of—

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007*. In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) of this chapter equals the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(e) *Decrease in monthly beneficiary premium for low-income assistance*. The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback prescription drug plans*. The monthly beneficiary premium charged under a fallback prescription drug plan is calculated under § 423.867(a) and not under this section, except that enrollees in fallback prescription drug plans are subject to late enrollment penalties under paragraph (d)(3) of this section and fallback prescription drug plan premiums are reduced or eliminated in the case of a subsidy-eligible individual, as described in paragraph (e) of this section.

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule*. Part D sponsors must charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage). Part D sponsors must also permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

(b) *Crediting of late enrollment penalty*. CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the Part D sponsor and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of the late enrollment.

(c) *Collection of late enrollment penalty*. (1) *Collection through withholding*. In the case of a late enrollment penalty that is collected by the government from a Part D eligible individual in the manner described in § 422.262(f)(1) of this chapter, CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the Part D sponsor offering the Part D plan in which the individual is enrolled.

(2) *Collection by plan*. In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1) of this chapter, CMS reduces payments otherwise made to the Part D plan by an amount equal to the portion of the late enrollment penalty.

(d) *Special rule for fallback plans*. This section does not apply to fallback prescription drug plans. The fallback plans follow the requirements set forth in § 423.867(b).

Subpart G—Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This subpart sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. This subpart does not apply to fallback entities or fallback prescription drug plans.

§ 423.308 Definitions and terminology.

For the purposes of this subpart, the following definitions apply-

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other

price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor for the drug.

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Allowable risk corridor costs means the subset of actually paid costs for covered Part D drugs (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor under the Part D plan. Costs must be based upon imposition of the maximum amount of copayments permitted under § 423.782. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any prescription drug coverage costs determined to be attributable to increased utilization over standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Coverage year means a calendar year in which covered Part D drugs are dispensed if the claim for those drugs (and payment on the claim) is made not later than 3 months after the end of the year

Gross covered prescription drug costs means those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees during the coverage year and costs relating to the deductible. They equal-

(1) All reimbursement paid by a Part D sponsor to a pharmacy (or other intermediary) or to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining drugs under the Part D plan; plus

(2) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost-sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain drugs covered under the Part D plan. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

Target amount for any Part D plan equals the total amount of payments (from both CMS and by or on behalf of enrollees) to that plan for the coverage year for all standardized bid amounts as risk adjusted under § 423.329(b)(1), less the administrative expenses (including return on investment) assumed in the standardized bids.

§ 423.315 General payment provisions.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments.* CMS provides a direct subsidy in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the monthly beneficiary premium as determined in § 423.286.

(c) *Reinsurance subsidies.* CMS provides reinsurance subsidy payments described in § 423.329(c) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under § 423.329(c)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies.* CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible individuals as provided in § 423.780 and § 423.782. CMS provides low-income

cost-sharing subsidy payments described in § 423.782 through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to actual allowable reinsurance costs as provided in § 423.343(d).

(e) *Risk-sharing arrangements.* CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the Part D plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year as provided in § 423.336.

(f) *Retroactive adjustments and reconciliations.* CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343.

(g) *Special rules for private fee-for-service plans.*

(1) *Application of reinsurance.* For private fee-for-service plans (as defined by § 422.4(a)(3) of this chapter) offering qualified prescription drug coverage, CMS determines the amount of reinsurance payments as provided under § 423.329(c)(3).

(2) *Exemption from risk corridor provisions.* The provisions of § 423.336 regarding risk sharing do not apply.

§ 423.322 Requirement for disclosure of information.

(a) *Payment conditional upon provision of information.* Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) *Restriction on use of information.* Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities. This restriction does not limit OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

§ 423.329 Determination of payments.

(a) *Subsidy payments.* (1) *Direct subsidy.* CMS makes a direct subsidy payment for each Part D eligible beneficiary enrolled in a Part D plan for a month equal to the amount of the plan's approved standardized bid, adjusted for health status (as determined under § 423.329(b)(1)), and reduced by the base beneficiary premium for the plan (as determined under § 423.286(c) and adjusted in § 423.286(d)(1)). The direct subsidy payment may be increased by the excess amount of a negative premium as described in § 423.286(d)(1), if applicable.

(2) *Subsidy through reinsurance.* CMS makes reinsurance subsidy payments as provided under paragraph (c) of this section.

(3) *Low-income cost-sharing subsidy.* CMS makes low-income cost-sharing subsidy payments as provided under paragraph (d) of this section.

(b) *Health status risk adjustment.* (1) *Establishment of risk factors.* CMS establishes an appropriate methodology for adjusting the standardized bid amount to take into account variation in costs for basic prescription drug coverage among Part D plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

(2) *Considerations.* In establishing the methodology under paragraph (b)(1) of this section, CMS takes into account the similar methodologies used under § 422.308(c) of this chapter to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(3) *Data collection.* In order to carry out this paragraph, CMS requires—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the

organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary.

(4) *Publication.* At the time of publication of risk adjustment factors under § 422.312(a)(1)(ii) of this chapter, CMS publishes the risk adjusters established under this paragraph of this section for the upcoming calendar year.

(c) *Reinsurance payment amount.* (1) *General rule.* The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) Payments during the coverage year. CMS establishes a payment method by which payments of amounts

under this section are made on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs.

(ii) *Final payments.* CMS reconciles the payments made during the coverage year to final actual allowable reinsurance costs as provided in § 423.343(c).

(3) *Special rules for private fee-for-service Plans offering prescription drug coverage.* CMS determines the amount of reinsurance payments for private fee-for-service plans as defined by § 422.4(a)(3) of this chapter offering qualified prescription drug coverage using a methodology that—

(i) Bases the amount on CMS' estimate of the amount of the payments that are payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act; and

(ii) Takes into account the average reinsurance payments made under § 423.329(c) for populations of similar risk under MA-PD plans described in section 1851(a)(2)(A)(i) of the Act.

(d) *Low-income cost sharing subsidy payment amount.*

(1) *General rule.* The low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a Part D plan for a coverage year is the amount described in § 423.782.

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) *Interim payments.* CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the low-income cost-sharing assumptions submitted with plan bids under § 423.265(d)(2)(iv) and negotiated and approved under § 423.272.

(ii) *Final payments.* CMS reconciles the interim payments to actual incurred low-income cost-sharing costs as provided in § 423.343(d).

§ 423.336 Risk-sharing arrangements.

(a) *Portion of total payments to a Part D sponsor subject to risk.* (1) *Adjusted allowable risk corridor costs.* For purposes of this paragraph, the term adjusted allowable risk corridor costs means—

(i) The allowable risk corridor costs for the Part D plan for the coverage year, reduced by—

(ii) The sum of—

(A) The total reinsurance payments made under § 423.329(c) to the Part D sponsor of the Part D plan for the year; and

(B) The total non-premium subsidy payments made under § 423.782 to the Part D sponsor of the Part D plan for the coverage year.

(2) *Establishment of risk corridors.* (i) *Risk corridors.* For each year, CMS establishes a risk corridor for each Part D plan. The risk corridor for a plan for a coverage year is equal to a range as follows:

(A) *First threshold lower limit.* The first threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(B) *Second threshold lower limit.* The second threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(C) *First threshold upper limit.* The first threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(D) *Second threshold upper limit.* The second threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(ii) *First and second threshold risk percentage defined.* (A) *First threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the first threshold risk percentage is for—

(*1*) 2006 and 2007, 2.5 percent;

(*2*) 2008 through 2011, 5 percent; and

(*3*) 2012 and subsequent years, a percentage CMS establishes, but in no case less than 5 percent.

(B) *Second threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the second threshold risk percentage is for—

(1) 2006 and 2007, 5.0 percent;

(2) 2008 through 2011, 10 percent

(3) 2012 and subsequent years, a percentage CMS establishes that is greater than the percent established for the year under paragraph (a)(2)(ii)(A)(3) of this section, but in no case less than 10 percent.

(iii) *Reduction of risk percentage to ensure two Plans in an area.* In accordance with § 423.265(e), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section. Only a PDP sponsor may request a reduction of risk under this paragraph. An MA organization offering an MA-PD plan, a PACE program offering qualified prescription drug coverage, and a cost-based HMO or CMP offering qualified prescription drug coverage may not request a reduction of risk under this paragraph.

(3) *Plans at risk for entire amount of supplemental prescription drug coverage.* A Part D sponsor that offers a Part D plan that provides supplemental prescription drug benefits is at full financial risk for the provision of the supplemental benefits.

(b) *Payment adjustments.* (1) *No adjustment if adjusted allowable risk corridor costs within risk corridor.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (a)(2)(i)(A) of this section) but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (a)(2)(i)(C) of this section) for the Part D plan for the coverage year, CMS makes no payment adjustment.

(2) *Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor.*

(i) *Costs between first and second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) *Costs above second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the second threshold upper limit of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions specified in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(B) 80 percent of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) *Conditions for application of higher percentage for 2006 and 2007.* The conditions specified in this paragraph are met for 2006 or 2007 if CMS determines for the year that—

(A) At least 60 percent of Part D plans to which this paragraph applies have adjusted allowable risk corridor costs for the Part D plan for the year that are more than the first threshold upper limit of the risk corridor for the Part D plan for the year; and

(B) Such plans represent at least 60 percent of Part D eligible individuals enrolled in any Part D plan.

(3) *Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor.*

(i) *Costs between first and second threshold lower limits.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D plan for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and the adjusted allowable risk corridor costs.

(ii) *Costs below second threshold lower limit.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less the second threshold lower limit of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D sponsor for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(B) 80 percent of the difference between the second threshold upper limit of the risk corridor and the adjusted allowable risk corridor costs.

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS will not make payments under this section if the Part D sponsor fails to provide the cost data information in paragraph (c)(1) of this section.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Lump sum and adjusted monthly payments.* CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year, as determined under this section.

(d) *No effect on monthly premium.* No adjustment in payments made by reason of this section may affect the monthly beneficiary premium for qualified prescription drug coverage.

§ 423.343 Retroactive adjustments and reconciliations.

(a) *Application of enrollee adjustment.* The provisions of § 422.308(f) of this chapter apply to payments to Part D sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a) of the Act.

(b) *Health status.* CMS makes adjustments to payments made under § 423.329(a)(1) to account for updated health status risk adjustment data as provided under § 422.310(g)(2) of this chapter. CMS may recover payments associated with health status adjustments if the Part D sponsor fails to provide the information described in § 423.329(b)(3).

(c) *Reinsurance.* CMS makes final payment for reinsurance after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between monthly reinsurance payments made during the coverage year and the amount payable in § 423.329(c) for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if the monthly reinsurance payments made during the coverage year exceed the amount payable under § 423.329(c) or if the Part D sponsor does not provide the data in paragraph (c)(1) of this section.

(d) *Low-income cost-sharing subsidy.* CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the Part D sponsor does not provide the data in paragraph (d)(1) of this section. In the event adequate data is not provided for risk corridor costs, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount.

§ 423.346 Reopening.

(a) CMS may reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336)—

(1) For any reason, within 12 months from the date of the notice of the final determination to the Part D sponsor

(2) After that 12-month period, but within 4 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening; or

(3) At any time, in instances of fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor.

(b) For purposes of this section, CMS will find good cause if—

(1) New and material evidence that was not readily available at the time the final determination was made is furnished;

(2) A clerical error in the computation of payments was made; or

(3) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(c) For purposes of this section, CMS will not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the final determination was made.

(d) A decision not to reopen under this section is final and is not subject to review.

§ 423.350 Payment appeals.

(a) *Payment determinations.* (1) *Payment methods subject to appeal.* If CMS did not apply its stated payment methodology correctly, a Part D sponsor may appeal the following:

(i) The reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b).

(ii) The reconciled reinsurance payments under § 423.343(c).

(iii) The reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); or

(iv) Final risk-sharing payments made under § 423.336).

(2) *Payment information not subject to appeal.* Payment information submitted to CMS under § 423.322 and reconciled under § 423.343 is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

(b) *Request for reconsideration.* (1) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the adverse determination.

(2) *Content of request.* The request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for the disagreements. Excluding new payment information, the request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(3) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the payment determination, the evidence and findings upon which it was based, and any other written evidence submitted by the Part D sponsor or by CMS before notice of the reconsidered determination is made.

(4) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the Part D sponsor on the sponsor's request.

(5) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (c) of this section, or it is revised in accordance with § 423.346.

(c) *Right to informal hearing.* A Part D sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the Part D sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor, explaining the basis for the decision.

(5) *Effecting of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (d) of this section.

(d) *Review by the Administrator.* (1) A Part D sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

Subpart H [Reserved]

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

§ 423.401 General requirements for PDP sponsors.

(a) *General requirements.* Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) *Licensure.* Except in cases where there is a waiver as specified at § 423.410 or § 423.415, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. If not otherwise licensed, the sponsor obtains certification from the State that the organization meets a level of financial solvency and other standards as the State may require for it to operate as a PDP sponsor.

(2) *Assumption of financial risk for unsubsidized coverage.* The PDP sponsor assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b) of the Act.

(b) *Reinsurance permitted.* The PDP sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage.

(c) *Solvency for unlicensed sponsors.* In the case of a PDP sponsor that is not described in § 423.401(a)(1) and for which a waiver is approved under § 423.410 or § 423.415, the sponsor must meet the requirements in § 423.420.

§ 423.410 Waiver of certain requirements to expand choice.

(a) *Authorizing waiver.* In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the entity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (b), (c), or (d) of this section are met.

(b) *Grounds for approval of waivers.* Subject to the waiver requirements specified in § 423.410(e), waivers may be granted under any of the following conditions:

(1) *Failure to act on licensure application on a timely basis.* The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State denied the license application on either of the following bases—-

(i) The State imposed material requirements,

procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) The State required, as a condition of licensure, that the organization offer any product or plan other than a prescription drug plan.

(3) *Denial of application based on application of solvency requirements.* The State denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements and

(i) The solvency requirements are different from the solvency standards CMS establishes in accordance with § 423.420; or

(ii) CMS determines that the State imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes in accordance with § 423.420.

(4) *Grounds other than those required by Federal Law.* The application by a State of any grounds other than those required under Federal law.

(c) *Waiver when licensing process not in effect.* The grounds for approval specified in paragraph (b)(1) of this section are deemed met if CMS determines that the State does not have a licensing process in effect for PDP sponsors.

(d) *Special waiver for plan years beginning before January 1, 2008.* For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process in effect, CMS grants a waiver upon a demonstration that an applicant to become a PDP sponsor has submitted a fully completed application for licensure to the State.

(e) *Waiver requirements.* The following rules apply to waiver applications or waivers granted under this section.

(1) *Treatment of waiver.* The waiver applies only to that State, is effective for 36 months, and cannot be renewed.

(2) *Prompt action on application.* CMS grants or denies a waiver application under this section within 60 days after CMS determines that a substantially complete waiver application is received by CMS.

(3) *A State that does not have a PDP sponsor.* In the case of a State that does not have a PDP sponsor licensing process, the 36 month limitation on the waiver discussed in paragraph (e)(1) of this section does not apply, and the waiver may continue in effect for a given State as long as CMS determines that the State does not have a PDP sponsor licensing process in effect, and the PDP sponsor meets the solvency standards of § 423.420(a).

§ 423.415 Temporary waivers for entities seeking to offer a prescription drug plan in more than one State in a region

(a) *General rule.* Subject to paragraphs (b) and (c) of this section, if an applicant seeking to become a PDP sponsor wishes to operate in more than one State in a region, and is licensed as a risk bearing entity in at least one State in the region, then the applicant may receive a temporary regional plan waiver for the States in which it is not licensed.

(b) *Filing of application.* The applicant must demonstrate to the satisfaction of CMS that it filed the necessary licensure applications with each State in the region for which it does not already have State licensure, except that no application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

(c) *Processing of application for temporary waiver.* The Secretary determines the time period appropriate for the timely processing of the application for temporary waiver.

(d) *Time limit for temporary waiver.* The temporary waiver expires at the end of time period that the Secretary determines is appropriate for timely processing of the application by the State or States, but in no case is a waiver extend beyond the end of the calendar year.

§ 423.420 Solvency standards for non-licensed entities.

(a) *Establishment and publication.* CMS establishes and publishes reasonable financial solvency and capital adequacy standards for entities specified in paragraph (b) of this section.

(b) *Compliance with standards.* A PDP sponsor that is not licensed by a State and for which a waiver application is approved by CMS under § 423.410 or § 423.415 must maintain reasonable financial solvency and capital adequacy in accordance with the standards established by CMS under paragraph (a) of this section.

§ 423.425 Licensure does not substitute for or constitute certification.

The fact that a Part D sponsor is State licensed or has a waiver application approved under § 423.410 or § 423.415 does not deem the sponsor to meet other requirements imposed under this part for a Part D sponsor.

§ 423.440 Prohibition of State imposition of premium taxes; relation to State laws.

(a) *Federal preemption of State law.* The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors.

(b) *State premium taxes prohibited.* (1) *Basic rule.* No premium tax, fee, or

other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities for any payment CMS makes on behalf of Part D plan or enrollees under this part (including the direct subsidy, reinsurance payments, and risk corridor payments); or for any payment made to Part D plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) *Construction*. Nothing in this section may be construed to exempt any Part D plan sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans; establishes waivers for MA-PD plans, employer-sponsored group prescription drug plans, cost plans, and PACE organizations; and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions.

For purposes of this part, the following definitions apply—

Employer-sponsored group prescription drug plan means prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage (as defined in § 423.882) approved by CMS as a prescription drug plan.

State Pharmaceutical Assistance Program (SPAP) means a State program that meets the requirements described under § 423.464(e)(1).

§ 423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

(a) *Relationship to Part C*. Except as otherwise provided in this Part, the requirements of this Part apply to prescription drug coverage provided by MA-PD plans offered by MA organizations beginning on or after January 1, 2006.

(b) *MA waiver*. CMS waives any provision of this Part otherwise applicable to MA-PD plans or MA organizations under paragraph (a) of this section to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organizations or MA-PD plans under Part C of Medicare, or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) *Application of waiver*. Any waiver or modification granted by CMS under this section applies to any other similarly situated organization offering or seeking to offer a MA-PD plan that meets the conditions of the waiver.

(2) *Request for waivers*. Organizations offering or

seeking to offer a MA-PD plan may request from CMS in writing—

(i) A waiver of those requirements under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section that are duplicative of, or that are in conflict with, provisions otherwise applicable to the MA-PD plan, proposed MA-PD plan, or a MA organization under Part C of Medicare.

(ii) A waiver of a requirement under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section, if such waiver improves coordination of benefits provided under Part C of Medicare with benefits under this Part.

(c) *Employer group waiver*. (1) *General rule*. CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible

individuals participating in the sponsor's employment-based retiree health coverage. Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

(2) *Use of waiver*. Waivers or modifications approved by CMS under this section apply to any similarly situated entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan, meeting the conditions of the waiver or modification.

(d) *Other waivers*. CMS waives any provision of this Part as applied to a cost plan (as defined in § 417.401 of this chapter) or PACE organization (as defined in § 460.6 of this chapter) that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the cost plan under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act, or as necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

(1) *Application of waiver*. Any waiver or modification granted by CMS under this paragraph applies to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as a cost plan under section 1876 of the Act or as a PACE organization under sections 1894 and 1934 of the Act.

(2) *Request for waivers*. Cost plans or PACE organizations seeking to offer qualified prescription drug coverage may request from CMS in writing-

(i) A waiver of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans or PACE organizations.

(ii) A waiver of a requirement under this part otherwise applicable to cost plans or PACE organizations, if such waiver improves coordination of benefits provided by the cost plan under section 1876 of the Act, or by the PACE organization under section 1934 of the Act, with the benefits under Part D.

§ 423.462 Medicare secondary payer procedures.

The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to Part D sponsors and Part D plans (with respect to the offering of qualified prescription drug coverage) in the same way as they apply to MA organizations and MA plans under Part C of title XVIII of the Act, except all references to MA organizations and MA plans are considered references to Part D sponsors and Part D plans.

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

(a) *General rule*. A Part D plan must permit SPAPs (described in paragraph (e)(1) of this section) and entities providing other prescription drug coverage (described in paragraph (f)(1) of this section) to coordinate benefits with such plan. A Part D plan must comply with all administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between such plan and SPAPs and entities providing other prescription drug coverage for—

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(f)(1)(ii)(including payment to a Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or entity providing other prescription drug coverage.

(b) *Medicare as primary payer*. The requirements of this subpart do not change or affect the primary or secondary payer status of a Part D plan and a SPAP or other prescription drug coverage. A Part D plan is always the primary payer relative to a State Pharmaceutical Assistance Program.

(c) *User fees*. CMS may impose user fees on Part D plans for the transmittal of information necessary for benefit coordination in accordance

with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and SPAPs and entities providing other prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B) of the Act, except that CMS may retain a portion of user fees to defray its costs in carrying out such procedures. CMS will not impose user fees under this subpart on a SPAP or entities providing other prescription drug coverage.

(d) *Cost management tools.* The requirements of this subpart do not prevent a Part D sponsor from using cost management tools (including differential payments) under all methods of operation.

(e) *Coordination with State Pharmaceutical Assistance Programs.* (1) *Requirements to be a State Pharmaceutical Assistance Program (SPAP).* A State program is considered to be a State Pharmaceutical Assistance Program for purposes of this part if it-

(i) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(ii) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(iii) Meets the benefit coordination requirements specified in this subpart;

(iv) Does not follow or adopt rules that change or affect the primary payer status of a Part D plan.

The definition of SPAP excludes State Medicaid programs, section 1115 demonstration programs, and any other program where program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding; and

(v) Provides supplemental drug coverage to individuals based on financial need, age, or medical condition, and not based on current or former employment status.

(2) *Use of a single card.* A card that is issued under § 423.120(c) for use under a Part D plan may also be used in connection with coverage of benefits provided under a SPAP and, in such a case, may contain an emblem or symbol indicating such connection.

(3) *Construction.* Nothing in this subpart requires a SPAP to coordinate with, or provide financial assistance to enrollees in, any Part D plan.

(f) *Coordination with other prescription drug coverage.* (1) *Definition of other prescription drug coverage.* Entities that provide other prescription drug coverage include any of the following:

(i) *Medicaid programs.* A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) Group health plans.

(iii) *FEHBP.* The Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code.

(iv) *Military coverage (including TRICARE).* Coverage under chapter 55 of title 10, United States Code.

(v) *Indian Health Service.* Coverage under Chapter 18 of title 28 of the United States Code.

(vi) *Federally qualified health centers.* Federally qualified health centers as defined under section 1861(aa)(4) of the Act.

(vii) *Rural health centers.* Rural health centers as defined under section 1861(aa)(2) of the Act.

(viii) *Other prescription drug coverage.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS may specify.

(2) *Treatment under out-of-pocket rule.* A Part D plan must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under § 423.104(d)(5)(iii). A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

(3) *Imposition of fees.* A Part D sponsor may not impose fees on SPAPs and entities offering other prescription drug

coverage that are unrelated to the cost of the coordination of benefits.

(4) *Authority to recover expenditures due to incorrect information on true out-of-pocket costs.* In the event that a Part D plan learns that it has made an erroneous payment due to inaccurate or incomplete information on the satisfaction of the out-of-pocket threshold under § 423.104(d)(5)(iii), that plan is authorized to recover such costs directly from the Part D enrollee on whose behalf the costs were incurred. A Part D enrollee must reimburse the Part D plan for payment made for these costs.

Subpart K—Application Procedures and Contracts with Part D plan sponsors

§ 423.500 Scope.

This subpart sets forth application procedures and contracts with Part D plans: application procedures and requirements; contract terms; procedures for termination of contracts; reporting by Part D plans. For purposes of this subpart, Medicare Advantage (MA) organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.

§ 423.501 Definitions

For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Related entity means any entity that is related to the PDP sponsor by common ownership or control and—

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a

cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the Part D plan sponsor, have a total value that exceeds $25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

§ 423.502 Application requirements.

(a) *Scope.* This section sets forth application requirements for an entity that seeks a determination from CMS that it is qualified to contract as a sponsor of a Part D plan.

(b) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete a certified application in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the requirements described in this part.

(c) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity is qualified to contract as a Part D plan sponsor and meets the requirements of this part.

(2) A CMS determination that an entity is qualified to act as a Part D plan sponsor is distinct from the bid negotiations that occur under subpart F of part 423 and such negotiations are not subject to the appeals provisions included in subpart N of this part.

(d) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 USC 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exemptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exemption specified in 45 CFR part 5.

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an entity's application on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, publicly available information, and any other appropriate procedures.

(2) After evaluating all relevant information, CMS determines whether the application meets the applicable requirements specified in § 423.504 and § 423.505.

(b) *Use of information from a prior contracting period.* If a Part D plan sponsor fails to comply with the terms of a previous year's contract (or in the case of a fallback entity, the previous 3-year contract) with CMS under title XVIII of the Act, or fails to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(c) *Notice of determination.* Except for fallback entities, which are governed under subpart Q of this part, CMS notifies each applicant that applies to be determined qualified to contract as a Part D plan sponsor, under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as Part D plan sponsor.

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear qualified to contract as a Part D plan sponsor and/or has not provided enough

information to evaluate the application, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the notice, the applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its application to remedy any defects CMS identified.

(3) Denial of application. If CMS denies the application, it gives written notice to the applicant indicating—

(i) That the applicant is not qualified to contract as a Part D sponsor under Part D of title XVIII of the Act;

(ii) The reasons why the applicant does is not so qualified; and

(iii) The applicant's right to request reconsideration in accordance with the procedures specified in subpart N.

(d) *Oversight of continuing compliance.* (1) CMS oversees a Part D plan sponsor's continued compliance with the requirements for a Part D plan sponsor.

(2) If a Part D plan sponsor no longer meets those requirements, CMS terminates the contract in accordance with § 423.509.

§ 423.504 General provisions.

(a) *General rule.* Subject to the provisions at § 423.265(a)(1) concerning submission of bids, to enroll beneficiaries in any Part D drug plan it offers and be paid on behalf of Part D eligible individuals enrolled in those plans, a Part D plan sponsor must enter into a contract with CMS. The contract may cover more than one Part D plan.

(b) *Conditions necessary to contract as a Part D plan sponsor.* Any entity seeking to contract as a Part D plan sponsor must—

(1) Complete an application as described in § 423.502 demonstrating that the entity has the capability to meet the requirements of this Part, including those listed in § 423.505.

(2) Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Part D plan, or have secured a Federal waiver, as described in subpart I of this part. (Fallback entity applicants need not be licensed as risk-bearing entities, nor are they required to obtain State licensure demonstrating that the applicant is eligible to offer health insurance or health benefits coverage in each State in which it applies to operate.)

(3) Meet the minimum enrollment requirements of § 423.512(a) unless waived under § 423.512(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the Part D plan sponsor's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the Part D plan sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the Part D sponsor, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the Part D plan sponsor.

(v)Insurance policies or other arrangements, secured and maintained by the Part D plan sponsor and approved by CMS to insure the Part D plan sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) A compliance plan that consists of the following—

(A)Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.

(B)The designation of a compliance officer and compliance committee accountable to senior management.

(C)Effective training and education between the compliance officer and organization employees, contractors, agents, and directors.

(D)Effective lines of communication between the compliance officer and the organization's employees, contractors, agents, directors, and members of the compliance committee.

(E)Enforcement of standards through well-publicized disciplinary guidelines.

(F) Procedures for effective internal monitoring and auditing.

(G) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a Part D plan sponsor.

(*1*) If the Part D sponsor discovers evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct;

(*2*) The Part D sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation referenced above.

(H) A comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority.

(5) Not have non-renewed a contract under §423.507 within the past 2 years unless—

(i) During the 6-month period, beginning on the date the entity notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing Part D sponsor payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(6) For a full risk or limited risk PDP applicant, not submitted a bid or offered a fallback prescription drug plan in accordance with the following rules.

(i) CMS does not contract with a potential PDP sponsor for the offering of a full risk or limited risk prescription drug plan in a PDP region for a year if the applicant—

(A) Submitted a bid under §423.863 for the year (as the first year of a contract period under §423.863 to offer a fallback prescription drug plan in any PDP region;

(B) Offers a fallback prescription drug plan in any PDP region during the year; or

(C) Offered a fallback prescription drug plan in that PDP region during the previous year.

(ii) *Construction*. For purposes of this paragraph (b)(6), an entity is treated as submitting an application to become qualified to contract as a full risk or limited risk PDP sponsor, if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of a full risk or limited risk PDP sponsor or applicant. The previous sentence does not apply to entities that are subcontractors of an MA organization except insofar as the MA organization is applying to act as a full risk or limited risk PDP sponsor.

(c) *Contracting authority*. CMS may enter into contracts under this part, or in order to carry out this part, without regard to Federal and Departmental acquisition regulations set forth in Title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections*. (1) CMS annually audits the financial records (including, but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs) under this part of at least one-third of the Part D sponsors offering Part D drug plans.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS, has the right to—

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the Part D plan sponsor's contract;

(ii) Inspect or otherwise evaluate the facilities of the Part D sponsor when there is reasonable evidence of some need for the inspection; and

(iii) Audit and inspect any books, contracts, and records of the Part D plan sponsor that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts.* The contract must provide that, upon CMS' request—

(1) The contract could be amended to exclude any State-licensed entity, or a Part D plan specified by CMS; and

(2) A separate contract for any excluded plan or entity must be deemed to be in place when a request is made.

§ 423.505 Contract provisions.

(a) *General rule.* The contract between the Part D plan sponsor and CMS must contain the provisions specified in paragraph (b) of this section.

(b) *Requirements for contracts.* The Part D plan sponsor agrees to—

(1) All the applicable requirements and conditions set forth in this part and in general instructions.

(2) Accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(3) Comply with the prohibition in § 423.34(a) on discrimination in beneficiary enrollment.

(4) Provide the basic prescription drug coverage as defined under § 423.100 and, to the extent applicable, supplemental benefits as defined in § 423.100. (Fallback entities may offer only standard prescription drug coverage as specified in § 423.855.)

(5) Disclose information to beneficiaries in the manner and the form specified by CMS under § 423.128.

(6) Operate quality assurance, cost and utilization management, medication therapy management, and support e-prescribing as required under subpart D of this part.

(7) Comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals, and formulary exceptions.

(8) Comply with the reporting requirements in § 423.514 and the requirements in § 423.329(b) for submitting drug claims and related information to CMS for its use in risk adjustment calculations.

(9) Provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this part (or for fallback entities, the information necessary to carry out the payment provisions in subpart Q of this part).

(10) Allow CMS to inspect and audit any books and records of a Part D plan sponsor that pertain to the information regarding costs provided to CMS under paragraph (b)(9) of this section, or, if a fallback entity, the information submitted under subpart Q.

(11) Be paid under the contract in accordance with the payment rules in subpart G of this part, or, if a fallback entity, in accordance with the payment rules of subpart Q of this part.

(12) Except for fallback entities, submit a future year's bid, including all required information on premiums, benefits, and cost-sharing, by any applicable due date, as provided in subpart F so that CMS and the Part D plan sponsor may conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan renewal.

(13) Permit CMS to determine that it is not qualified to renew its contract or that its contract may be terminated in accordance with this subpart and subpart N of this part. (Subpart N applies to fallback entities only to the extent a fallback contract is terminated.)

(14) Comply with the confidentiality and enrollee record accuracy specified in § 423.136.

(15) Comply with State law and preemption by Federal law requirements described in subpart I of this part.

(16) Comply with the coordination requirements with SPAPs and plans that provide other prescription drug coverage as described in subpart J of this part.

(17) Provide benefits by means of point of service systems to adjudicate in a drug claims in a timely and efficient manner in compliance with CMS standards, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in § 423.100), and long-term care pharmacies (as defined in § 423.100).

(18) To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.

(c) *Communication with CMS.* The Part D plan sponsor must have the capacity to communicate with CMS electronically in accordance with CMS requirements.

(d) *Maintenance of records.* The Part D plan sponsor agrees to maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices that-

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid of part D plan sponsors).

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the Part D plan sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Except for fallback entities, properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the Part D plan sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs (as defined in § 423.308).

(v) Except for fallback entities, establish the basis for the components, assumptions, and analysis used by the Part D plan in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in § 423.265(c)(3).

(2) Include records of the following:

(i) Ownership and operation of the Part D sponsor's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other actions.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Matters pertaining to costs of operations.

(viii) Amounts of income received by source and payment.

(ix) Cash flow statements.

(x) Any financial reports filed with other Federal programs or State authorities.

(xi) All prescription drug claims for the current contract period and 10 prior periods.

(xii) All price concessions (including concessions offered by manufacturers) for the current contract period and 10 prior periods accounted for separately from other administrative fees.

(e) *Access to facilities and records.* The Part D plan sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the Part D plan sponsor; and

(iii) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical record s, patient care documentation, and other records of the Part D plan sponsor, related entity(s), contractor(s), subcontractor(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract,

or as the Secretary may deem necessary to enforce the contract.

(3) The Part D plan sponsor agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Part D plan sponsor at least 30 days before the normal disposition date;

(ii) There is a termination, dispute, or allegation of fraud or similar fault by the Part D plan sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the Part D plan sponsor at any time.

(f) *Disclosure of information.* The Part D plan sponsor agrees to submit to CMS—

(1) Certified financial information that must include the following:

(i) Information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Information as CMS may require pertaining to the disclosure of ownership and control of the Part D plan sponsor.

(2) All information to CMS that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information includes, but is not limited to:

(i) The benefits covered under a Part D plan.

(ii) The Part D plan monthly basic beneficiary premium and Part D plan monthly supplemental beneficiary premium, if any, for the plan. Fallback entities submit the monthly beneficiary premium for standard prescription drug coverage.

(iii) The service area of each plan.

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) The recent records regarding compliance of the plan with requirements of this part, as determined by CMS; and

(D) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice regarding Part D plans.

(v) Information about beneficiary appeals and their disposition, and formulary exceptions.

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

(vii) Information on other matters that CMS may require, including, but not limited to, program monitoring and oversight, performance measures, quality assessment, research and evaluation, CMS outreach activities, payment-related oversight*, and fraud, abuse, and waste*, as specified in CMS guidelines.

(viii) Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

(3)To its enrollees, all informational requirements under § 423.128 and, upon an enrollee's request, the financial disclosure information required under § 423.128(c)(4).

(g) *Beneficiary financial protections.* The Part D plan sponsor agrees to comply with the following requirements:

(1) Each Part D plan sponsor must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the Part D sponsor. To meet this requirement, the Part D plan sponsor must—

(i) Ensure that all contractual or other written arrangements prohibit the sponsor's contracting agents from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the Part D plan sponsor for covered prescription drugs furnished by non-contracting pharmacists, or that have not otherwise entered into an agreement with the Part D plan sponsor, to provide services to the organization's beneficiary enrollees.

(2) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the Part D plan sponsor may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.*

The Part D plan sponsor agrees to comply with-

(1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. §§ 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

(2) HIPAA Administrative Simplification rules at 45 CFR parts 160, 162, and 164.

(i) *Relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the Part D plan sponsor may have with related entities, contractors, or subcontractors, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The Part D plan sponsor agrees to require all related entities, contractors, or subcontractors to agree that—

(i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to CMS' contract with the Part D plan sponsor; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between Part D plan sponsors and pharmacies or other providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit pharmacies or other providers from holding an enrollee liable for payment of any fees that are the obligation of the Part D plan sponsor.

(ii) Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a pharmacy, related entity, contractor, or subcontractor only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the Part D plan sponsor's contractual obligations.

(4) If any of the Part D plan sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or pharmacy:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting responsibilities described in paragraph (i)(4)(i) of this section or specify other remedies in instances when CMS or the Part D plan sponsor determine that the parties have not performed satisfactorily.

(iii) Written arrangements must specify that the Part D plan sponsor on an ongoing basis monitors the performance of the parties.

(iv) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

(5) If the Part D plan sponsor delegates selection of its prescription drug providers to another organization, the Part D sponsor's written arrangements with that organization must state that the CMS-contracting Part D plan sponsor retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The Part D plan sponsor agrees to include in the contract other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Certification of data that determine payment.*

(1) *General rule.* As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part),, the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) *Certification of enrollment and payment information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) *Certification of claims data.* The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

(4) *Certification of bid submission information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265.

(5) *Certification of allowable costs for risk corridor and reinsurance information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs, as defined in § 423.308, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(6) *Certification of Accuracy of Data for Price Comparison.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers,

and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of price comparison is accurate, complete, and truthful.

§ 423.506 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the Part D plan sponsor and CMS.

(b) *Term of contract.* Each contract is for a period of 12 months.

(c) *Qualification to renew a contract.* In accordance with § 423.507 of this subpart, an entity is determined qualified to renew its contract annually only if—

(1) CMS informs the Part D plan sponsor that it is qualified to renew its contract; and

(2) The Part D plan sponsor has not provided CMS with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although a Part D plan sponsor may be determined qualified to renew its contract under this section, if the sponsor and CMS cannot reach agreement on the bid under subpart F, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in subpart N of this part.

(e) The provisions of this section do not apply to fallback entities.

§ 423.507 Nonrenewal of contract.

(a) *Nonrenewal by a Part D plan sponsor.* (1) Except for fallback entities, a Part D plan sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a Part D plan sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the PDP region, including MA-PD plans , and other PDPs, and must receive CMS approval prior to issuance; and

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(3) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(4) If a Part D plan sponsor does not renew a contract under this paragraph (a), it must ensure the timely transfer of any data or files.

(b) *CMS decision that a Part D plan sponsor is not qualified to renew.* (1) Except for fallback entities, CMS may determine that a Part D plan sponsor is not qualified to renew its contract for any of the following reasons:

(i) The reasons listed in § 423.509(a) that also permit CMS to terminate the contract.

(ii) The Part D plan sponsor has committed any of the acts in § 423.752 that support the imposition of intermediate sanctions or civil money penalties under § 423.750.

(2) *Notice of decision.* CMS provides notice of its decision of whether a Part D plan sponsor is qualified to renew its contract as follows:

(i) To the Part D plan sponsor by May 1 of the current contract year.

(ii) If CMS decides that a Part D plan sponsor is not qualified to renew its contract, to the Part D plan sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If CMS determines that the Part D plan sponsor is not qualified to renew its contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) The notice provisions in paragraphs (b)(2)(ii) and (iii) of this section also apply in cases where a non-renewal results because CMS and the Part D plan sponsor are unable to reach agreement on the bid under subpart F.

(3) *Notice of appeal rights.* CMS gives the Part D plan sponsor written notice of its right to appeal the decision that the sponsor is not qualified renew its contract in accordance with § 423.642(b).

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent.

(b) *Notification of termination.* If the contract is terminated by mutual consent, the Part D plan sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

(c) *Notification of modification.* If the contract is modified by mutual consent, the Part D plan sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(d) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons if the Part D sponsor—

(1) Failed substantially to carry out the terms of its contract with CMS;

(2) Is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part;

(3) No longer meets the requirements of this part for being a contracting organization;

(4) There is credible evidence that the Part D sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data;

(5) Experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists;

(6) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals;

(7) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.322 and § 423.329 (or, for fallback entities, fails to provide the information in § 423.871(f)).

(8) Substantially fails to comply with the service access requirements in § 423.120;

(9) Substantially fails to comply with the marketing requirements in § 423.128;

(10) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part; or

(11) Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subparts D and K of this part.

(b) *Notice of termination.* If CMS decides to terminate a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the Part D plan in writing 90 days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The Part D plan sponsor notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) If a Part D plan sponsor's contract is terminated under paragraph (a) of this section, it must ensure the timely transfer of any data or files.

(2) *Immediate termination of contract by CMS.* (i) For terminations based on violations specified in paragraph (a)(4) or paragraph (a)(5) of this section, CMS notifies the Part D plan sponsor in writing that its contract is terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the prospective monthly payments made to the Part D sponsor covering the period of the month following the contract termination.

(ii) CMS notifies the Part D plan sponsor's Medicare enrollees in writing of CMS's decision to terminate the Part D plan sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the Part D plan sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining qualified prescription drug coverage, including alternative PDP sponsors and MA-PDs in a similar geographic area.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(c) *Corrective action plan.* (1) *General rule.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, CMS provides the Part D plan sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception.* If a contract is terminated under paragraph (a)(4) or (a)(5) of this section, the Part D plan sponsor does not have the opportunity to submit a corrective action plan.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the Part D plan sponsor informing it of its termination appeal rights in accordance with § 423.642.

§ 423.510 Termination of contract by the Part D sponsor.

(a) *Cause for termination.* The Part D plan sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice of termination.* The Part D plan sponsor must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the Part D sponsor is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the services area, including alternative PDPs, MA-PDPs, and original Medicare and must receive CMS approval.

(3) To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the Part D plan sponsor's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the Part D plan sponsor ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(f) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

§ 423.512 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this

subpart unless the organization meets the following minimum enrollment requirement:

(1) At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or

(2) At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) of this chapter;

(3) Except as provided for in paragraph (b) of this section, a Part D plan sponsor must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver*. CMS waives the requirement of paragraphs (a)(1) and (a)(2) of this section during the first contract year for a sponsor in a region.

§ 423.514 Reporting requirements.

(a) *Required information*. Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following—

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation.

(5) Other matters that CMS may require.

(b) *Significant business transactions*. Each Part D plan sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions, as defined in § 423.501, between the Part D plan sponsor and a party in interest, including the following:

(i) Indication that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(2) A combined financial statement for the Part D plan sponsor and a party in interest if either of the following conditions is met:

(i) Thirty five percent or more of the costs of operation of the Part D sponsor go to a party in interest.

(ii) Thirty five percent or more of the revenue of a party in interest is from the Part D plan sponsor.

(c) *Requirements for combined financial statements*. (1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the Part D plan sponsor and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a Part D plan sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA)*. (1) For any employees' health benefits plan that includes a Part D plan sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The PDP sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(e) *Loan information*. Each Part D plan sponsor must notify CMS of any

loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information.* Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

§ 423.551 General provisions.

(a) *Change of ownership.* The following constitute a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer.* Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* (1) A PDP sponsor that has a Medicare contract in effect under § 423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS that—

(1) Is embodied in a document executed and signed by all 3 parties;

(2) Meets the requirements of § 423.552; and

(3) Recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(f) *Effect of change of ownership with novation agreement.* If the PDP sponsor submits a novation agreement that meets the requirements of § 423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under § 423.502.

§ 423.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The PDP sponsor submits to CMS, at least 30 days before the proposed

change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination*. When reviewing a novation agreement, CMS makes a determination concerning the following:

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement*. A valid novation agreement requires the following:

(1) *Assumption of contract obligations*. The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement*. The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance*. The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access*. The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing*. If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities*. (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities*. If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, and Appeals

§ 423.560 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Projected value means the charges incurred by the enrollee and future charges that are incurred within 12 months from the date the request for coverage determination or exception is received by the plan. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

Reconsideration means a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

§ 423.562 General provisions.

(a) *Responsibilities of the Part D plan sponsor*. A Part D plan sponsor must meet all of the following requirements.

(1) A Part D plan sponsor, for each Part D plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) A procedure for making timely coverage determinations, including determinations on requests for exceptions to a tiered cost-sharing structure or to a formulary; and

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(2) A Part D plan sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the Part D plan sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) A Part D plan sponsor must arrange with its network pharmacies to post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.

(4) In accordance with subpart K of this part, if the Part D plan sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the Part D plan sponsor provides covered benefits, the Part D plan sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of enrollees*. In accordance with the provisions of this subpart, enrollees have all of the following rights under Part D plans:

(1) The right to have grievances between the enrollee and the Part D plan sponsor heard and resolved by the plan sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the Part D plan sponsor, as specified in § 423.566 and § 423.568, including the right to request from the Part D plan sponsor an exception to its tiered cost-sharing structure or formulary, as specified in § 423.578.

(3) The right to request from the Part D plan sponsor an expedited coverage determination, as specified in § 423.570.

(4) If dissatisfied with any part of a coverage determination, all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of a redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) If the IRE affirms the plan's adverse coverage determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.610.

(v) If the ALJ affirms the IRE's adverse coverage determination, in whole or in part, the right to request MAC review of the ALJ hearing decision, as specified in § 423.620.

(vi) If the MAC affirms the ALJ's adverse coverage determination, in whole or in part, the right to judicial review of the hearing decision if the amount in controversy meets the requirements in § 423.630.

(c) *When other regulations apply*. Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

(d) *Relation to ERISA Requirements*. Consistent with section 1860D–22(b) of the Act, provisions of this subpart may, to the extent applicable under the regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

§ 423.564 Grievance procedures.

(a) *General rule*. Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Part D plan sponsor or any other entity or individual through whom the Part D plan sponsor provides covered benefits under any Part D plan it offers.

(b) *Distinguished from appeals*. Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process*. Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the Part D plan sponsor. For quality of care issues, an enrollee may file a grievance with the Part D plan sponsor, file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance*. (1) An enrollee may file a grievance with the Part D plan sponsor either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification*. (1) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the Part D plan sponsor receives the oral or written grievance.

(2) The Part D plan sponsor may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

(3) The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the

Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* A Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination under § 423.570 or an expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.

(g) *Record keeping.* The Part D plan sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the enrollee was notified of the disposition.

§ 423.566 Coverage determinations.

(a) Responsibilities of the Part D plan sponsor. Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in § 423.100 and supplemental benefits as specified in § 423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) Actions that are coverage determinations. The following actions by a Part D plan sponsor are coverage determinations:

(1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

(3) A decision concerning an exceptions request under § 423.578(a);

(4) A decision concerning an exceptions request under § 423.578(b); or

(5) A decision on the amount of cost sharing for a drug.

(c) Who can request a coverage determination. Individuals who can request a standard or expedited coverage determination are—

(1) The enrollee;

(2) The enrollee's appointed representative, on behalf of the enrollee; or

(3) The prescribing physician, on behalf of the enrollee.

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's supporting statement.

(b) *Timeframe for requests for payment.* When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the request.

(c) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(d) *Form and content of the denial notice.* The notice of any denial under paragraph (c) of this section must—

Use approved notice language in a readable and understandable form;

State the specific reasons for the denial;

Inform the enrollee of his or her right to a redetermination;

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process;

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process; and

Comply with any other notice requirements specified by CMS.

(e) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (a) or (b) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

§ 423.570 Expediting certain coverage determinations.

(a) *Request for expedited determination.* An enrollee or an enrollee's prescribing physician may request that a Part D plan sponsor expedite a coverage determination involving issues described in § 423.566(b). This does not include requests for payment of Part D drugs already furnished.

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or an enrollee's prescribing physician on behalf of the enrollee must submit an oral or written request directly to the Part D plan sponsor, or if applicable, to the entity responsible for making the determination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited determination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited determinations:

(1) An efficient and convenient means for accepting oral or written requests submitted by enrollees or prescribing physicians.

(2) A method for documenting all oral requests and maintaining the documentation in the case file; and

(3) A means for issuing prompt decisions on expediting a determination, based on the following requirements:

(i) For a request made by an enrollee, provide an expedited determination if it determines that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by an enrollee's prescribing physician, provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If a Part D plan sponsor denies a request for expedited determination, it must take the following actions:

(1) Make the determination within the 72 hour timeframe established in § 423.568(a) for a standard determination. The 72 hour period begins on the day the Part D plan sponsor receives the request for expedited determination, or, for an exceptions request, the physician's supporting statement.

(2) Give the enrollee and prescribing physician prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor must process the request using the 72 hour timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support; and

(iv) Provides instructions about the plan's grievance process and its timeframes.

(3) Subsequently deliver, within 3 calendar days, equivalent written notice.

(e) *Actions on accepted requests for expedited determination.* If a Part D plan sponsor grants a request for expedited determination, it must make the determination and give notice in accordance with § 423.572.

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determinations and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement.

(b) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(c) Content of the notice of expedited determination.

(1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a redetermination;

(ii) Describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(d) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the timeframe specified in paragraph (a) of this section, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

§ 423.576 Effect of a coverage determination.

The coverage determination is binding on the Part D plan sponsor and the enrollee unless it is reviewed and revised under § 423.580 through § 423.630 or is reopened and revised under § 423.634.

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's statement under paragraph (a)(4) of this section.

(1) The exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) The exceptions criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a determination made by the enrollee's prescribing physician under paragraph (a)(4) of this section.

(ii) Consideration of whether the requested Part D drug that is the subject of the exceptions request is the therapeutic equivalent, as defined in § 423.100, of any other drug on the plan's formulary.

(iii) Consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested prescription drug that is the subject of the exceptions request.

(3) An enrollee or the enrollee's prescribing physician may file a request for an exception.

(4) A prescribing physician must provide an oral or written supporting statement that the preferred drug for the treatment of the enrollee's condition—

(i) Would not be as effective for the enrollee as the requested drug;

(ii) Would have adverse effects for the enrollee; or

(iii) Both paragraphs (a)(4)(i) and (a)(4)(ii) of this section apply.

(5) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement to demonstrate the medical necessity of the drug. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(6) In no case is a Part D plan sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier dedicated to generic drugs.

(7) If a Part D plan sponsor maintains a formulary tier in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception.

(b) *Request for exceptions involving a non-formulary Part D drug.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain exceptions procedures subject to CMS' approval for receipt of an off-formulary drug. The Part D plan sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug. Formulary use includes the application of cost utilization tools, such as a dose restriction, including the dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.

(1) The plan's formulary exceptions process must address each of the following circumstances:

(i) Situations where a formulary changes during the year, and situations where an enrollee is already using a given drug.

(ii) Continued coverage of a particular Part D prescription drug that the Part D plan sponsor is discontinuing coverage on the formulary for reasons other than safety or because the Part D prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a plan's coverage policy that causes a Part D prescription drug not to be covered because of cost utilization tools, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.

(2) The exception criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a prescribing physician's determination made under paragraph (b)(5) of this section;

(ii) A process for gathering and comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug for the enrollee, including safety information generated by an authoritative government body; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(3) If the Part D plan sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold.

(4) An enrollee, the enrollee's appointed representative, or the prescribing physician (on behalf of the enrollee) may file a request for an exception.

(5) A prescribing physician must provide an oral or written supporting statement that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) All of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee; or

(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(6) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(c) *Requirements for exceptions.* (1) *General rule.* A decision by a Part D plan sponsor concerning an exceptions request under this section constitutes a coverage determination as specified at §423.566.

(2) When a Part D plan sponsor does not make a timely decision. If the Part D plan sponsor fails to make a decision on an exceptions request and provide notice of the decision within the timeframe required under §423.568(a) or §423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under §423.578(a) is approved, the Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies for preferred drugs, and may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(i) The enrollee's prescribing physician continues to prescribe the drug;

(ii) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(iii) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(4) *When a non-formulary exceptions request is approved.* Whenever an exceptions request made under §423.578(b) is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under §423.578(b).

(d) *Notice regarding formulary changes.* Whenever a Part D plan sponsor removes a covered part D drug from its formulary or makes any changes in the

preferred or tiered cost-sharing status of such a drug, the Part D plan sponsor must provide notice in accordance with § 423.120(b)(5).

(e) *Limitation of the exceptions procedures to Part D drugs.* Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug.

(f) *Implication of the physician's supporting statement.* Nothing in this section should be construed to mean that the physician's supporting statement required for an exceptions request will result in an automatic favorable determination.

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.634) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. An enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) may request an expedited redetermination specified in § 423.584.

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, an enrollee must file a request for a redetermination within 60 calendar days from the date of the notice of the coverage determination.

(c) *Extending the time for filing a request.* (1) *General rule.* If an enrollee shows good cause, the Part D plan sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor. The request for redetermination and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for redetermination was not filed on time.

(d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a written request with the Part D sponsor.

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b). (This does not include requests for payment of drugs already furnished.)

(b) *How to make a request.* (1) To ask for an expedited redetermination, an enrollee or a prescribing physician acting on behalf of an enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited redetermination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The Part D plan sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision making.* The Part D plan sponsor must promptly decide whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the Part D plan sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life

or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician, the Part D plan sponsor must provide an expedited redetermination if the physician indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial of a request.* If a Part D plan sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Make the determination within the 7-day timeframe established in § 423.590(a). The 7-day period begins the day the Part D plan sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor processes the enrollee's request using the 7-day timeframe for standard redetermination;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's support; and

(iv) Provides instructions about the expedited grievance process and its timeframes.

(3) Subsequently deliver, within three calendar days, equivalent written notice.

(e) *Action following acceptance of a request.* If a Part D plan sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

§ 423.586 Opportunity to submit evidence.

The Part D plan sponsor must provide the enrollee or the prescribing physician, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the Part D plan sponsor must inform the enrollee or the prescribing physician of the conditions for submitting the evidence.

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *Standard redetermination—request for covered drug benefits.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1)) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(b) *Standard redetermination—request for payment.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 7 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 7 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redeterminations.* If the Part D plan sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to

the IRE within 24 hours of the expiration of the adjudication timeframe.

(d) *Expedited redetermination.* (1) *Timeframe.* A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) How the Part D plan sponsor must request additional information. If the Part D plan sponsor must receive medical information, the Part D plan sponsor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the timeframe and notice requirements.

(e) *Failure to meet timeframe for expedited redetermination.* If the Part D plan sponsor fails to provide the enrollee or the prescribing physician, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(f) *Who must conduct the review of an adverse coverage determination.* (1) A person or persons who were not involved in making the coverage determination must conduct the redetermination.

(2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2) or (b)(2) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(i) For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;

(ii) For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

(4) Comply with any other notice requirements specified by CMS.

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. An enrollee must file a written request for reconsideration with the IRE within 60 days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician. The IRE may solicit the views of the prescribing physician orally or in writing. A written account of the prescribing physician's views (prepared by either the prescribing physician or IRE, as appropriate) must be contained in the IRE's record.

(c) In order for an enrollee to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed

the deadlines applicable in § 423.590, including those deadlines that are applicable when a request for an expedited reconsideration is received and granted.

(e) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

(2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.610;

(3) Describe the procedures that must be followed to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.612.

§ 423.610 Right to an ALJ hearing.

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs shall include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(c) *Aggregating appeals to meet the amount in controversy.* (1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and

(iii) The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

The appeals have previously been reconsidered by an IRE;

The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and

The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.

§ 423.612 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in part 422, subpart M of this chapter, the enrollee must file a request for a hearing within 60 days of the date of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will

be set in accordance with § 405.1020 of this chapter.

(c) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.610, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.610, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 423.620 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal. The regulations under part 422, subpart M of this chapter regarding MAC review apply to matters addressed by this subpart, to the extent applicable.

§ 423.630 Judicial review.

(a) *Review of ALJ's decision.* The enrollee may request judicial review of an ALJ's decision if—

(1) The MAC denied the enrollee's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* The enrollee may request judicial review of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) How to request judicial review. In order to request judicial review, an enrollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. (See part 422, subpart M of this chapter, for a description of the procedures to follow in requesting judicial review.)

§ 423.634 Reopening and revising determinations and decisions.

(a) A coverage determination or redetermination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 422, subpart M of this chapter.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) *Reversals by the Part D plan sponsor.* (1) *Requests for benefits.* If, on redetermination of a request for benefit, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 7 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor.* (1) *Requests for benefits.* If, on appeal of a request for benefit, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Requests for payment.* If, on appeal of a request for payment, the determination by the Part D plan sponsor is

reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize payment for the benefit within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

(a) *Reversals by the Part D plan sponsor*. If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor*. If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

Subpart N—Medicare Contract Determinations and Appeals

§ 423.641 Contract determinations.

This subpart establishes the procedures for reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A determination not to authorize a renewal of a contract with a PDP sponsor in accordance with § 423.507(b).

(c) A determination to terminate a contract with a PDP sponsor in accordance with § 423.509.

(d) Fallback entities are governed under subpart Q of this part, and are not subject to this subpart, except to the extent a fallback prescription drug plan contract is terminated by CMS.

§ 423.642 Notice of contract determination.

(a) When CMS makes a contract determination under § 423.641, it gives the PDP sponsor written notice.

(b) The notice specifies the—

(1) Reasons for the determination; and

(2) PDP sponsor's right to request reconsideration.

(c) For CMS-initiated terminations, CMS mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at § 423.509(a)(4) or (a)(5), CMS immediately notifies the PDP sponsor of its decision to terminate the organization's PDP contract.

(d) When CMS determines that it is not going to authorize a contract renewal, CMS mails the notice to the PDP sponsor by May 1 of the current contract year.

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with § 423.644 through § 423.649;

(b) A timely request for a hearing is filed under § 423.651; or

(c) The reconsideration decision is revised as a result of a reopening under § 423.668.

§ 423.644 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in § 423.641.

(b) CMS reconsiders the specified determinations if the contract applicant or the PDP sponsor files a written request in accordance with § 423.645.

§ 423.645 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or PDP sponsor that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The PDP sponsor or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS.

§ 423.646 Opportunity to submit evidence.

CMS provides the PDP sponsor or contract applicant and the CMS official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which a PDP sponsor chooses to request a hearing as described at § 423.651, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

§ 423.647 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the PDP sponsor subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

(c) Any favorable redetermination, including those resulting from a hearing or Administrator review, must be made by July 15 for the contract in question to be effective on January of the following year.

§ 423.648 Notice of reconsidered determination.

(a) CMS gives the PDP sponsor or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings for the contract applicant's qualifications to enter into, or the PDP sponsor's qualifications to remain under, a contract with CMS under Part D of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the PDP sponsor or contract applicant of its right to a hearing if it is dissatisfied with the determination.

§ 423.649 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with § 423.651 or it is revised in accordance with § 423.668.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may

be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) Exception: A contract terminated in accordance with § 423.509(a)(4) or (a)(5) is immediately terminated and is not postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by the Administrator*. A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 423.665(b).

(b) *Review by the Administrator*. The Administrator must review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator*. The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination*. CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination.

(b) *Decision of hearing officer*. A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by

the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator*. A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices*. (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

Subpart O—Intermediate Sanctions

§ 423.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from $10,000 to $100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the Part D sponsor for Medicare beneficiaries who enroll.

(4) Suspension of all Part D plan marketing activities to Medicare beneficiaries for the Part D plan subject to the intermediate sanctions.

(b) The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based is corrected and is not likely to recur.

§ 423.752 Basis for imposing sanctions.

(a) *All intermediate sanctions*. For the violations listed below, we may impose one, or more, of the sanctions specified in § 423.750(a)(2), (a)(3) or (a)(4) on any Part D sponsor that has a contract in effect. The Part D sponsor may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to a Part D plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D–1 *et seq*. of the Act and subpart F of this part.

(3) Acts to expel or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing*. If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may instead impose the intermediate sanctions in § 423.750(a)(2) and (a)(4).

§ 423.756 Procedures for imposing sanctions.

(a) *Notice of sanction and opportunity to respond*.

(1) Notice of sanction. Before imposing the intermediate sanctions specified in paragraph (c) of this section, CMS—

(i) Sends a written notice to the Part D sponsor stating the nature and basis of the proposed sanction; and

(ii)Sends the Office of the Inspector General a copy of the notice.

(2) *Opportunity to respond.* CMS allows the Part D sponsor 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements described in § 423.752, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the Part D sponsor. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the Part D sponsor's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration.* If, consistent with paragraph (a)(2) of this section, the Part D sponsor submits a timely response to CMS' notice of sanction, CMS conducts an informal reconsideration that—

(1) Consists of a review of the evidence by an CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the Part D sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions.* If CMS determines that a Part D sponsor has acted or failed to act as specified in § 423.752 and affirms this determination in accordance with paragraph (b) of this section, CMS may—

(1) Require the Part D sponsor to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned plan during the sanction period;

(2) In the case of a violation under § 423.752(a), suspend payments to the Part D sponsor for Medicare beneficiaries enrolled in the sanctioned plan during the sanction period; and

(3) Require the Part D sponsor to suspend all marketing activities for the sanctioned plan to Medicare enrollees.

(d) *Effective date and duration of sanctions.* (1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the Part D sponsor seeks reconsideration in a timely manner under paragraph (b) of this section, on the date specified in the notice of CMS' reconsidered determination.

(2) *Exception.* If CMS determines that the Part D sponsor's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS' reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the Part D sponsor that CMS is satisfied that the basis for imposing the sanction is corrected and is not likely to recur.

(e) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b)(2) and (b)(3), or terminate the contract in accordance with § 423.509.

(f) *Civil money penalties.* (1) If CMS determines that a Part D sponsor has committed an act or failed to comply with a requirement described in § 423.752, CMS notifies the OIG of this determination, and also notifies OIG when CMS reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in § 423.752(a), or a determination under § 423.752(b) based upon a violation under § 423.509(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1003 of this chapter, the OIG may impose civil money penalties on the Part D sponsor in accordance with part 1003 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 423.752(b) other than a determination based upon a violation under § 423.509(a)(4), CMS may impose civil money penalties on the Part D sponsor in the amounts specified in § 423.758 in

addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

§ 423.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 423.509(a), as described in § 423.752(b), excepting those determinations under § 423.509(a)(4), CMS may impose civil money penalties, in addition to, or in place of, the sanctions that CMS may impose under § 423.756(c), in the following amounts:

(a) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D plan enrollees—up to $25,000 for each determination.

(b)For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to $10,000 per week.

(c)If CMS makes a determination that a Part D sponsor has terminated its contract with CMS other than in a manner described in § 423.510 and that the sponsor has therefore failed to substantially carry of the terms of the contract, $250 per Medicare enrollee from the terminated Part D plan or plans at the time the Part D sponsor terminated its contract, or $100,000, whichever is greater.

§ 423.760 Other applicable provisions.

The provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§ 423.771 Basis and scope.

(a) *Basis*. This subpart is based on section 1860D–14 of the Act.

(b) *Scope*. This subpart sets forth the requirements and limitations for payments by and on behalf of low-income Medicare beneficiaries who enroll in a Part D plan.

§ 423.772 Definitions.

For purposes of this subpart, the following definitions apply:

Applicant means the Part D eligible individual applying for the subsidies available to subsidy eligible individuals under this subpart.

Family size means the applicant, the spouse who is living in the same household, if any and the number of individuals who are related to the applicant or applicants, who are living in the same household and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support.

Federal poverty line (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 USC 9902(2)), including any revision required by that section.

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus program demonstrations or under a section 1115 demonstration that provides pharmacy-only benefits to these individuals.). It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month.

Full subsidy means the subsidies available to full subsidy eligible individuals under § 423.780(a) and § 423.782(a).

Full subsidy eligible individuals means individuals meeting the eligibility requirements under § 423.773(b).

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is, as defined by section 1612 of the Act). This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

Institutionalized individual means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act.

Other subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773(d).

Personal representative for purposes of this subpart means—

(1) An individual who is authorized to act on behalf of the applicant;

(2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or

(3)An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Resources means liquid resources of the applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located.

State means for purposes of this subpart each of the 50 States and the District of Columbia.

§ 423.773 Requirements for eligibility

(a) *Subsidy eligible individual.* A subsidy eligible individual is a Part D eligible individual residing in a State who is enrolled in, or seeking to enroll in a Part D plan and meets the following requirements:

(1) Has income below 150 percent of the FPL applicable to the individual's family size.

(2) Has resources at or below the resource thresholds set forth in § 423.773(b)(2) or (d)(2).

(b) *Full subsidy eligible individual.* A full subsidy eligible individual is a subsidy eligible individual who—

(1) Has income below 135 percent of the FPL applicable to the individual's family size; and

(2)Has resources that do not exceed—

(i) For 2006, 3 times the amount of resources an individual may have and still be eligible for benefits under the Supplemental Security Income (SSI) program under title XVI of the Act (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the amount of resources allowable for the previous year under this paragraph (b)(2) increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of that previous year, rounded to the nearest multiple of $10. The nearest multiple are rounded up if it is equal to or greater than $5 and down if it is less than $5.

(c)(1) *Individuals treated as full subsidy eligible.* An individual must be treated as meeting the eligibility requirements for full subsidy eligible individuals under paragraph (b) of this section if the individual is a—

(i) Full-benefit dual eligible individual;

(ii) Recipient of SSI benefits under title XVI of the Act; or

(iii) Eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan.

(2) CMS notifies an individual treated as a full subsidy eligible under this paragraph (c) of this section that he or she does not need to apply for the subsidies available under this subpart, and is deemed eligible for a full subsidy for a period up to one year.

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who—

(1) Have income less than 150 percent of the FPL applicable to the individual's family size; and

(2) Have resources that do not exceed—

(i) For 2006, $10,000 if single or $20,000 if married (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the resource amount

allowable for the previous year under this paragraph (d)(2), increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of $10. The nearest multiple will be rounded up if it is equal to or greater than $5 and down if it is less than $5.

§ 423.774 Eligibility determinations, redeterminations, and applications.

(a) *Determinations of whether an individual is a subsidy eligible individual.* Determinations of eligibility for subsidies under this subpart are made by the State under its State plan under title XIX of the Act if the individual applies with the Medicaid agency, or if the individual applies with the Social Security Administration (SSA), the Commissioner of Social Security in accordance with the requirements of section 1860D–14(a)(3) of the Act.

(b) *Effective date of initial eligibility determinations.* Initial eligibility determinations are effective beginning with the first day of the month in which the individual applies, but no earlier than January 1, 2006 and remain in effect for a period not to exceed 1 year.

(c) *Redeterminations and appeals of low-income subsidy eligibility.*

(1) *Redeterminations and appeals of low-income subsidy eligibility determinations—eligibility determinations made by States.* Redeterminations and appeals of low-income subsidy eligibility determinations by States must be made in the same manner and frequency as the redeterminations and appeals are made under the State's plan.

(2) *Redeterminations and appeals of low-income subsidy eligibility—eligibility determinations made by Commissioner of Social Security.* Redeterminations and appeals of eligibility determinations made by the Commissioner will be made in the manner specified by the Commissioner of Social Security.

(d) *Application requirements.* (1) In order for applications for the subsidies under this subpart to be considered complete, applicants or personal representatives applying on the individual's behalf, must—

(i) Complete all required elements of the application; (ii) Provide any statements from financial institutions, as requested, to support information in the application; and

(iii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(2) Multiple applications. If the individual or his or her personal representative has previously filed an application with the State or SSA which seeks subsidy eligibility for any portion of the eligibility period covered by a subsequent application, the later application is void if the individual has received a positive subsidy determination on that earlier application from the State or SSA.

§ 423.780 Premium subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to a premium subsidy equal to 100 percent of the premium subsidy amount.

(b) *Premium subsidy amount.*

(1) The premium subsidy amount is equal to an amount which is the lesser of:

(i) Under the Part D plan selected by the beneficiary, the monthly beneficiary premium for a Part D plan other than a MA-PD plan that is basic prescription drug coverage, the portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a Part D plan other than a MA-PD plan that is enhanced alternative coverage, or the MA monthly prescription drug beneficiary premium as defined under section 1854(b)(2)(B) of the Act, or

(ii) The greater of the low-income benchmark premium amount for a PDP region as determined under paragraph (b)(2) of this section or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the PDP region.

(2) *Calculation of the low-income benchmark premium amount.* (i) The low-income benchmark premium amount for a PDP region is a weighted average

of the premium amounts described in this paragraph (b)(2)(ii) of this section , with the weight for each PDP and MA-PD plan equal to a percentage, the numerator being equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in all PDP and MA-PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans)in a PDP region in the reference month.

(ii) Premium amounts: The premium amounts used to calculate the low-income benchmark premium amount are as follows:

(A) The monthly beneficiary premium for a PDP that is basic prescription drug coverage;

(B) The portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a PDP that is enhanced alternative coverage; or,

(C)The MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Act) for a MA-PD plan.

(c) *Special rule for 2006 to weight the low-income benchmark premium.* For purposes of calculating the low-income benchmark premium amount for 2006, CMS assigns equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. New MA-PD plans are assigned a zero weight. PACE, private fee-for-service plans and 1876 cost plans are not included.

(d) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

(1) For individuals with income at or below 135 percent of the FPL applicable to their family size, the full premium subsidy amount.

(2) For individuals with income greater than 135 percent but at or below 140 percent of the FPL applicable to the family size, a premium subsidy equal to 75 percent of the premium subsidy amount.

(3) For individual with income greater than 140 percent but at or below 145 percent of the FPL applicable to the family size a premium subsidy equal to 50 percent of the premium subsidy amount.

(4) For individuals with income greater than 145 percent but below 150 percent of FPL applicable to the family size a premium subsidy equal to 25 percent of the premium subsidy amount.

(e) *Premium subsidy for late enrollment penalty.* Full subsidy eligible individuals who are subject to late enrollment penalties under § 423.46 are entitled to an additional premium subsidy equal to 80 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 100 percent of their late enrollment penalty thereafter.

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(d)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA-PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104(d)(5)(A). This applies to both:

(A) those full-benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size and

(B) those individuals who have income under 135 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at § 423.773(b)(2).

(ii) Full-benefit dual eligible individuals who are institutionalized have no cost-sharing for covered Part D drugs covered under their PDP or MA-PD plans.

(iii) Full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered Part D drugs equal to the lesser of:

(A) A copayment amount of not more than $1 for a generic drug or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or $3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or

(B) The copayment amount charged to other individuals under this paragraph (a)(2)(i) of this section.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA-PD plan above the out-of-pocket limit (under § 423.104(d)(5)).

(b) *Other low-income subsidy eligible individuals*. Other low-income subsidy eligible individuals are entitled to the following:

(1) In 2006, reduction in the annual deductible to $50. This amount is increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for Part D drugs, rounded to the nearest multiple of $1.

(2) Fifteen percent coinsurance for all covered Part D drugs obtained after the annual deductible under the plan up to the out-of-pocket limit (under § 423.104(d)(5)(iii)).

(3) For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)), in 2006, copayments not to exceed $2 for a generic drug or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug. For years beginning in 2007, the amounts specified in section paragraph (b)(3) for the previous year increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

§ 423.800 Administration of subsidy program.

(a) *Notification of eligibility for low-income subsidy*. CMS notifies the Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy under this section and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization*. The Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information to CMS on the amount of those reductions, in a manner determined by CMS. The Part D sponsor must track the application of the subsidies under this subpart to be applied to the out-of-pocket threshold.

(c) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy*. The Part D sponsor offering the Part D plan must reimburse subsidy eligible individuals, and organizations paying cost-sharing on behalf of such individuals, any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy under this subpart.

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)

§ 423.851 Scope.

This subpart sets forth—the rights of beneficiaries to a choice of at least two sources of qualified prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug plans, and the determination of enrollee premium and plan payments for these plans.

§ 423.855 Definitions.

As used in this subpart, unless specified otherwise-

Actual costs means the subset of prescription drug costs (not including administrative costs or return on investment, but including costs directly related to the dispensing of covered Part

D drugs during the year) that are attributable to standard benefits only and that are incurred and actually paid by the sponsor or organization under the plan.

Actually paid has the same meaning described in § 423.308.

Eligible fallback entity or *fallback entity* means an entity that, for a particular contract period-

(1) Is a PDP sponsor that does not have to be a risk-bearing entity (or, if applying to become a fallback entity, an entity that meets all the requirements to become a Part D plan sponsor except that it does not have to be a risk-bearing entity); and

(2) Does not submit a risk bid under § 423.265 for offering a prescription drug plan for any PDP region for the first year of that contract period. An entity is treated as submitting a risk bid if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of an entity that is or applies to become a non-fallback PDP sponsor. An entity is not treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as or applies to become a non-fallback PDP sponsor for a prescription drug plan.

Fallback prescription drug plan means a prescription drug plan (PDP) offered by a fallback entity that—

(1) Offers only defined standard or actuarially equivalent standard prescription drug coverage as defined in § 423.100;

(2) Provides access to negotiated prices, including discounts from manufacturers; and

(3) Meets all other requirements established for prescription drug plans, except as otherwise specified by CMS in this subpart or in separate guidance.

Qualifying plan means a full-risk or limited-risk prescription drug plan, as defined in § 423.258, or an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act, that provides required prescription drug coverage, as defined in § 423.100 An MA-PD plan must be open for enrollment and not operating under a capacity waiver to be counted as a qualifying plan. A PDP must not be operating under a restricted enrollment waiver, such as those that may be granted to special needs plans or employer group plans, in order to be counted as a qualifying plan in an area.

§ 423.859 Assuring access to a choice of coverage.

(a) *Choice of at least 2 qualifying plans in each area.* Each Part D eligible individual must have available a choice of enrollment in at least 2 qualifying plans (as defined in § 423.855) in the area in which the individual resides. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. At least 1 of the 2 qualifying plans must be a prescription drug plan.

(b) *Fallback service area.* (1) *For coverage year.* Before the start of each coverage year CMS determines if Part D eligible individuals residing in a PDP region have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, do not have available a choice of enrollment in a minimum of two qualified plans, CMS designates the region or portion of a region as a fallback service area. Each Part D eligible individual in a fallback service area is given the opportunity to enroll in a fallback prescription drug plan.

(2) *For mid-year changes.* If a contract with a qualifying plan is terminated in the middle of a contract year (as provided for in § 423.508, § 423.509, or § 423.510), CMS determines if Part D eligible individuals residing in the affected PDP region still have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, no longer have available a choice of enrollment in a minimum of two qualifying plans, CMS designates the region or portion of a region as a fallback service area.

(c) *Access to coverage in the territories.* CMS may waive or modify the requirements of this part if—

(1) CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in a State other than the 50 States or the District of Columbia; or

(2) An entity seeking to become a prescription drug plan in an area such as a territory, other than the 50 States or the District of Columbia requests waiver or modification of any Part D requirement in order to provide qualified prescription drug coverage.

§ 423.863 Submission and approval of bids.

(a) *Submission of Bids.* (1) *Solicitation of bids.* Separate from the risk bidding process under § 423.265, CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan during the contract period specified in § 423.871(b).

(2) *Timing of bids.* CMS determines when to solicit bids for 2006 so that potential fallback prescription drug plans have enough time to prepare a bid. After that, bids are solicited on 3 year cycles, or annually thereafter as needed to replace contractors between contracting cycles.

(3) *Format of bid.* CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

(b) *Negotiation and acceptance of bids.*

(1) *General rule.* Except as provided in this section, the provisions of § 423.272 apply for the approval or disapproval of fallback prescription drug plans. CMS enters into contracts under this paragraph with eligible fallback entities for the offering of approved fallback prescription drug plans in potential fallback service areas.

(2) *Flexibility in risk assumed and application of fallback prescription drug plan.* In order to ensure access in an area in accordance with § 423.859(a), CMS may approve limited risk plans under § 423.272(c) for that area. If the access requirement is still not met after applying § 423.272(c), CMS provides for the offering of a fallback prescription drug plan in that area.

(3) *Limitation of 1 Plan for all fallback service areas in a PDP region.* All fallback service areas in any PDP region for a contract period must be served by the same fallback prescription drug plan.

(4) *Competitive procedures.* CMS uses competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) to enter into a contract under this paragraph. The provisions of section 1874A(d) of the Act apply to a contract under this section in the same manner as they apply to a contract under that section.

(5) *Timing of contracts.* CMS approves a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans are otherwise offered. In the event of mid-year changes and as required by § 423.859(b)(2), CMS approves a fallback prescription drug plan for a PDP region in a manner so that the fallback prescription drug plan is offered within 90 days of notice.

(6) *No national fallback prescription drug plan.* CMS may not enter into a contract with a single fallback entity for the offering of fallback prescription drug plans throughout the United States.

§ 423.867 Rules regarding premiums.

(a) *Monthly beneficiary premium.* Except as provided in § 423.286(d)(3) (relating to late enrollment penalty) and subject to subpart P (relating to low-income assistance), the monthly beneficiary premium under a fallback prescription drug plan must be uniform for all fallback service areas in a PDP region. It must equal 25.5 percent of CMS's estimate of the average monthly per capita actuarial cost, including administrative expenses, of providing coverage in the PDP region based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(b) *Special rule for collection of premiums in fallback prescription drug plans.* In the case of a fallback prescription drug plan, the provisions of § 423.293 (b) concerning payments of the late enrollment penalty to the PDP sponsor do not apply and the monthly beneficiary premium is collected in the manner specified in § 422.262(f)(1) of this chapter, or paid directly to the fallback entity by the beneficiary if there are either no benefits, or insufficient benefits available to be collected in the

manner specified under § 422.262(f)(1) of this chapter. The amount of any premiums collected by the fallback entity is deducted from management fees due from CMS.

§ 423.871 Contract terms and conditions.

(a) *General.* Except as may be appropriate to carry out the requirements of this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans are the same as the terms and conditions of contracts at § 423.504 and § 423.505 for Part D plans.

(b) *Period of contract.* A contract with a fallback entity for fallback service areas for a PDP region is in effect for a period of 3 years. However, a fallback prescription drug plan may be offered for any year within the contract period for a particular area only if the area is a fallback service area for that year.

(c) *Entity not permitted to market or brand fallback prescription drug plans.* Notwithstanding any other provisions of this part, an eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan.

(d) *Performance measures.* CMS issues guidance establishing performance measures for fallback prescription drug plans based on the following:

(1) *Types of performance measures.* Performance measures include at least measures for each of the following:

(i) *Costs.* The entity contains costs to the Medicare Prescription Drug Account and to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

(ii) *Quality programs.* The entity provides the enrollees in its fallback prescription drug plan with quality programs that avoid adverse drug reactions, monitor for appropriate utilization, and reduce medical errors.

(iii) *Customer service.* The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) *Benefit administration and claims adjudication.* The entity provides efficient and effective benefit administration and claims adjudication.

(2) *Development of performance measures.* CMS establishes detailed performance measures for use in evaluating fallback entity performance and determination of certain management fees based on criteria from historical performance, application of acceptable statistical measures of variation to fallback entity and PDP sponsor (other than fallback entities) experience nationwide during a base period, or changing program emphases or requirements.

(e) *Payment terms.* A contract approved with a fallback entity includes terms for payment for—

(1) The actual costs of covered Part D drugs provided to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(2) Management fees that consist of administrative costs and return on investment and are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract as provided under paragraph (d) of this section.

(f) *Requirement for the submission of information.* Each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the payment provisions under subpart G or under this subpart, or as required by law. Information disclosed to determine Medicare payment or reimbursement to the fallback entity may be used by the officers, employees and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, determining such payment or reimbursement. This restriction does not limit CMS or OIG authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement

(g) *Amendment to reflect changes in service area.* The contract may be amended by CMS at any time as needed to reflect the exact regions or counties where the fallback plan are required to

operate within the contracted service area(s).

§ 423.875 Payment to fallback plans.

The amount payable for a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) Basis. This subpart is based on section 1860D–22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) Scope. This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Allowable retiree costs, in accordance with section 1860D–22(a)(3)(C)(i) of the Act, means gross covered retiree plan-related prescription drug costs that are actually paid (net any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions) by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the qualifying covered retiree's behalf).

Benefit option means a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or *gross retiree costs means*, for a qualifying covered retiree who is enrolled in a qualified retiree prescription drug plan during a plan year, non-administrative costs incurred under the plan for Part D drugs during the year, whether paid for by the plan or the retiree, including costs directly related to the dispensing of Part D drugs.

Group health plans include plans as defined in section 607(1) of ERISA, 29 U.S.C. § 1167(1). They also include the following plans:

(1) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under chapter 89 of Title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) A collectively bargained plan, which is a plan providing medical care that is established or maintained under or by one or more collective bargaining agreements.

(3) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(4) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93, a health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2), a health savings account (HSA) as defined in Code section 223, or an Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C.§. § 1003(b), for governmental plans or church plans).

Part D drug is defined in § 423.100 of this part.

Part D eligible individual is defined in § 423.4 of this part.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 423.884 of this

chapter for a Part D eligible individual who is a retired participant or the spouse or dependent of a retired participant under the coverage.

Qualifying covered retiree means a Part D eligible individual who is: a participant or the spouse or dependent of a participant; covered under employment-based retiree health coverage that qualifies as a qualified retiree prescription drug plan; and not enrolled in a Part D plan. For this purpose, the determination of whether an individual is covered under employment-based retiree health coverage is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed not to be covered under employment-based retiree health coverage if, under the Medicare Secondary Payer rules in § 411.104 of this chapter and related CMS guidance, the person is considered to be receiving coverage by reason of current employment status. The presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor also may treat a person receiving coverage under its qualified retiree prescription drug plan as the dependent of a qualifying covered retiree in accordance with the rules of its plan, regardless of whether that person constitutes the qualifying covered retiree's dependent for Federal or State tax purposes.

Retiree drug subsidy amount, or subsidy payment, means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under § 423.886(a).

Standard prescription drug coverage is defined in § 423.100 of this part.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

Sponsor agreement means an agreement by the sponsor to comply with the provisions of this subpart.

§ 423.884 Requirements for qualified retiree prescription drug plans.

(a) *General*. Employment-based retiree health coverage is considered to be a qualified retiree prescription drug plan if all of the following requirements are satisfied:

(1) An actuarial attestation is submitted in accordance with paragraph (d) of this section. The rules for submitting attestations as part of subsidy applications are described in paragraph (c) of this section.

(2) Part D eligible individuals covered under the plan are provided with creditable coverage notices in accordance with § 423.56.

(3) Records are maintained and made available for audit in accordance with paragraph (f) of this section and § 423.888(d).

(b) *Disclosure of information*. The sponsor must have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103), or group health plan (as applicable) regarding disclosure of information to CMS, and the issuer or plan must disclose to CMS, on behalf of the sponsor, the information necessary for the sponsor to comply with this subpart.

(c) *Application*. (1) *Submitting an application*. The sponsor (or its designee) must submit an application for the subsidy to CMS that is signed by an authorized representative of the sponsor. The application must be provided in a form and manner specified by CMS.

(2) *Required information*. In connection with each application the sponsor (either directly or through its designee) must submit the following:

(i) Employer Tax ID Number (if applicable).

(ii) Sponsor name and address.

(iii) Contact name and email address.

(iv) Actuarial attestation that satisfies the standards specified in paragraph (d) of this section and any other supporting documentation required by CMS for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.

(v) A list of all individuals the sponsor believes (using information reasonably available to the sponsor when it submits the application) are qualifying covered retirees enrolled in each prescription drug plan (including spouses

and dependents, if Medicare-eligible), along with the information about each person listed below in this paragraph:

(A) Full name.

(B) Health Insurance Claim (HIC) number or Social Security number.

(C) Date of birth.

(D) Gender.

(E) Relationship to the retired employee.

(vi) A sponsor may satisfy paragraph (c)(2)(v) of this section by entering into a voluntary data sharing agreement (VDSA) with CMS (or any other arrangement CMS may make available).

(vii) A signed sponsor agreement.

(viii) Any other information specified by CMS.

(3) *Terms and conditions*. To receive a subsidy payment, the sponsor (through the signed sponsor agreement or as otherwise specified by CMS) must specifically accept and agree to:

(i) Comply with the terms and conditions of eligibility for a subsidy payment set forth in this regulation and in any related CMS guidance;

(ii) Acknowledge that the information in the application is being provided to obtain Federal funds; and

(iii) Require that all subcontractors, including plan administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds.

(4) *Signature by sponsor*. An authorized representative of the requesting sponsor must sign the completed application and certify that the information contained in the application is true and accurate to the best of the sponsor's knowledge and belief.

(5) *Timing*. (i) *General rule*. An application for a given plan year must be submitted by no later than 90 days prior to the beginning of the plan year, unless a request for an extension has been filed and approved under procedures established by CMS.

(ii) *Transition rule*. For plan years that end in 2006, an application must be submitted by September 30, 2005 unless a request for an extension has been filed and approved under procedures established by CMS.

(6) *Updates*. The sponsor (or the designee) must provide updates to CMS in a manner specified by CMS of the information required in paragraph (c)(2) of this section on a monthly basis or at a frequency specified by CMS.

(7) *Data match*. Once the full application for the subsidy payment is submitted, CMS—

(i) Matches the names and identifying information of the individuals submitted as qualifying covered retirees with the Medicare Beneficiary Database (MBD) to determine which retirees are Part D eligible individuals who are not enrolled in a Part D plan.

(ii) Provides information concerning the results of the search in paragraph (c)(7)(i) of this paragraph (such as names and other identifying information, if necessary) to the sponsor (or to a designee).

(d) *Actuarial attestation-general*. The sponsor of the plan must provide to CMS an attestation in a form and manner specified by CMS that the actuarial value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the defined standard prescription drug coverage (as defined at §423.100). The attestation must meet all of the following standards.

(1) Contents of the attestation include the following assurances:

(i) The actuarial gross value of the retiree prescription drug coverage under the plan for the plan year is at least equal to the actuarial gross value of the defined standard prescription drug coverage under Part D for the plan year in question.

(ii) The actuarial net value of the retiree prescription drug coverage under the plan for that plan year is at least equal to the actuarial net value of the defined standard prescription drug coverage under Part D for the plan year in question.

(iii) The actuarial values must be determined using the methodology in paragraph (d)(5) of this section.

(2) The attestation must be made by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries, including (but not limited to) actuaries employed by the plan administrator or an insurer providing benefits under the plan. If an applicant

uses an outside actuary, the attestation can be submitted directly by the outside actuary or by the plan sponsor.

(3)The attestation must be signed by a qualified actuary and must state that the attestation is true and accurate to the best of the attester's knowledge and belief.

(4) The attestation must contain an acknowledgement that the information being provided in the attestation is being used to obtain Federal funds.

(5) Methodology. (i) *Basis of the attestation.* The attestation must be based on generally accepted actuarial principles and any actuarial guidelines established by CMS in this section or in future guidance. To the extent CMS has not provided guidance on a specific aspect of the actuarial equivalence standard under this section, an actuary providing the attestation may rely on any reasonable interpretation of this section and section 1860D–22(a) of the Act consistent with generally accepted actuarial principles in determining actuarial values.

(ii) *Specific rules for determining the actuarial value of the sponsor's retiree prescription drug coverage.*

(A) The gross value of coverage under the sponsor's retiree prescription drug plan must be determined using the actual claims experience and demographic data for Part D eligible individuals who are participants and beneficiaries in the sponsor's plan, provided that sponsors without creditable data due to their size or other factors, may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(ii)(A).

(B) The net value of coverage provided under the sponsor's retiree prescription drug plan must be determined by reducing the gross value of such coverage as determined under paragraph (d)(5)(ii)(A) of this section by the expected premiums paid by Part D eligible individuals who are plan participants or their spouses and dependents. For sponsors of plans that charge a single, integrated premium or contribution to their retirees for both prescription drug coverage and other types of medical coverage, the attestation must allocate a portion of the premium/contribution to prescription drug coverage under the sponsor's plan, under any method determined by the sponsor or its actuary.

(iii) *Specific rules for calculating the actuarial value of defined standard prescription drug coverage under Part D.*

(A) The gross value of defined standard prescription drug coverage under Part D must be determined using the actual claims experience and demographic data for Part D eligible individuals in the sponsor's plan, provided that sponsors without credible data due to their size or other factors may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(iii)(A).

(B) To calculate the net value of defined standard prescription drug coverage under Part D, the gross value of defined standard prescription drug coverage under Part D as determined by paragraph (d)(5)(iii)(A) of this section is reduced by the following amounts:

(1) The monthly beneficiary premiums (as defined in § 423.286) expected to be paid for standard prescription drug coverage; and

(2) An amount calculated to reflect the impact on the value of defined standard prescription drug coverage of supplemental coverage provided by the sponsor. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified in this paragraph (d)(5)(iii)(B)(2).

(C) The valuation of defined standard prescription drug coverage for a given plan year is based on the initial coverage limit cost-sharing and out-of-pocket threshold for defined standard prescription drug coverage under Part D in effect at the start of such plan year. The attestation, however, must be submitted to CMS no later than 60 days after the publication of the Part D coverage limits for the upcoming calendar year otherwise, such valuation is based on the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold for defined standard prescription drug coverage under Part D for the upcoming calendar year.

(D) Example. If a sponsor's retiree prescription drug plan operates under a plan year that ends March 30, the attestation for the year April 1, 2007–March 30, 2008 is based on the coverage limit, cost-sharing and out-of-pocket threshold that apply to defined standard prescription drug coverage under Part D in 2007 provided the attestation is submitted within 60 days after the publication of the Part D coverage limits for 2008. If the attestation is submitted more than 60 days after the 2008 coverage limits have been published, the 2008 coverage limits would apply.

(iv) Employment-based retiree health coverage with two or more benefit options. For the assurance required under paragraph (d)(1)(i) of this section, the assurance must be provided separately for each benefit option for which the sponsor requests a subsidy under this subpart. For the assurance required under paragraph (d)(1)(ii) of this section, the assurance may be provided either separately for each benefit option for which the sponsor provided assurances under paragraph (d)(1)(i) of this section, or in the aggregate for all benefit options for which the sponsor provided assurances under paragraph (d)(1)(i) of this section.

(6) Timing. (i) *Annual submission*. The attestation must be provided annually at the time the sponsor's subsidy application is submitted, or at such other times as specified by CMS in further guidance.

(ii) *Submission following material change*. The attestation must be provided no later than 90 days before the implementation of a material change to the drug coverage of the sponsor's plan that impacts the actuarial value of the coverage.

(e) *Disclosure of creditable prescription drug coverage status*. The sponsor must disclose to all of its retirees and their spouses and dependents eligible to participate in its plan who are Part D eligible individuals whether the coverage is creditable prescription drug coverage under § 423.56 in accordance with the notification requirements under that section.

(f) *Access to records for audit*. The sponsor (and where applicable, its designee) must meet the requirements of § 423.888(d). Failure to comply with § 423.888(d) may result in nonpayment or recoupment of all or part of a subsidy payment.

§ 423.886 Retiree drug subsidy amounts.

(a) *Amount of subsidy payment*. (1) For each qualifying covered retiree enrolled with the sponsor of a qualified retiree prescription drug plan in a plan year, the sponsor receives a subsidy payment in the amount of 28 percent of the allowable retiree costs (as defined in § 423.882) in the plan year for such retiree attributable to gross retiree costs between the cost threshold and the cost limit as defined in paragraph (b) of this section. The subsidy payment is calculated by first determining gross retiree costs between the cost threshold and cost limit, and then determining allowable retiree costs attributable to the gross retiree costs. For this purpose and where otherwise relevant in this subpart, plan year is the calendar, policy, or fiscal year on which the records of a plan are kept.

(2) *Transition provision*. For a qualified retiree prescription drug plan that has a plan year which begins in calendar year 2005 and ends in calendar year 2006, the subsidy for the plan year must be determined in the following manner. Claims incurred in all months of the plan year (including claims incurred in 2005) are taken into account in determining which claims fall within the cost threshold and cost limit for the plan year. The subsidy amount is determined based only on costs incurred on and after January 1, 2006.

(b) *Cost threshold and cost limit*. The following cost threshold and cost limits apply—

(1) Subject to paragraph (b)(3) of this section, the cost threshold under this section is equal to $250 for plan years that end in 2006.

(2) Subject to paragraph (b)(3) of this section, the cost limit under this section is equal to $5,000 for plan years that end in 2006.

(3) The cost threshold and cost limit specified in paragraphs (b)(1) and (b)(2) of this section, for plan years that end in years after 2006, are adjusted in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually

under § 423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively.

§ 423.888 Payment methods, including provision of necessary information.

(a) *Basis.* The provisions of § 423.301 through § 423.343, including requirements to provide information necessary to ensure accurate subsidy payments, govern payment under § 423.886 except to the extent the provisions in this section specify otherwise.

(b) *General payment rules.* Payment under § 423.886 is conditioned on provision of accurate information. The information must be submitted, in a form and manner and at the times provided in this paragraph and under other guidance specified by CMS, by the sponsor or its designee.

(1) *Timing.* Payment can be made on a monthly, quarterly or annual basis, as elected by the plansponsor under guidance specified by CMS, unless CMS determines that the options must be restricted because of operational limitations.

(i) *Monthly or quarterly payments.* If the plan sponsor elects for payment on a monthly or quarterly basis, it must provide information described in paragraph (b)(2)(i) of this section on the same monthly or quarterly basis, or at such time as CMS specifies.

(ii) *Annual payments.* If the sponsor elects an annual payment, it must submit to CMS actual rebate and other price concession data within 15 months after the end of the plan year.

(2) *Submission of cost data.* (i) *Monthly or quarterly payments.* If the plan sponsor elects to receive payment on a monthly or quarterly basis, it must submit to CMS, in a manner specified by CMS, the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for its qualifying covered retirees during the payment period for which it is claiming a subsidy payment and any other data CMS may require. Except as otherwise provided by CMS in future guidance, the sponsor must also submit, using historical data and generally accepted actuarial principles, an estimate of the extent to which its expected allowable retiree costs differs from the gross covered retiree plan-related prescription drug costs, based on expected rebates and other price concessions for the upcoming plan year. The estimate must be used to reduce the periodic payments for the plan year. Final allocation of price concession data must occur after the end of the year under the reconciliation provisions of paragraph (b)(4) of this section

(ii) *Annual payments.* If the plan sponsor elects a one-time final annual payment, it must submit, in a manner specified by CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of the plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882) for the plan year for which it is claiming a subsidy payment, actual rebate and other price concession data described in paragraph (b)(1)(ii) of this section, and any other data CMS may require. The alternative is that the sponsor can elect an interim annual payment, in which case it must submit the following to CMS, at a time and in a manner specified by CMS: the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for all of its qualifying covered retirees during the payment period for which it is claiming a subsidy payment; an estimate (using historical data and generally accepted actuarial principles) of the difference between such gross costs and allowable costs (based on expected rebates and other price concessions for the upcoming plan year); and any other data CMS may require.

(3) *Payment by CMS.* CMS makes payment after the sponsor's submission of the cost data at a time and in a manner to be specified by CMS.

(4) *Reconciliation.* (i) Sponsors who elect either monthly, quarterly or an interim annual payment must submit to CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of its plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882), in a manner specified by CMS; actual rebate and other price concession data for the plan year in question; and any other data CMS may require.

(ii) Upon receiving this data, CMS adjusts the payments made for the plan

year in question in a manner to be specified by CMS.

(5) *Special rule for insured plans.* (i) *Interim payments.* Sponsors of group health plans that provide benefits through health insurance coverage (as defined in 45 CFR 144.103) and that choose either monthly payments, quarterly payments or an interim annual payment in paragraphs (b)(1) and (b)(2) of this section , may elect to determine gross covered plan-related retiree prescription drug costs for purposes of the monthly, quarterly or interim annual payments based on a portion of the premium costs paid by the sponsor (or by the qualifying covered retirees) for coverage of the covered retirees under the group health plan. Premium costs that are determined, using generally accepted actuarial principles, may be attributable to the gross prescription drug costs incurred by the health insurance issuer (as defined in 45 CFR § 144.103) for the sponsor's qualifying covered retirees, except that administrative costs and risk charges must be subtracted from the premium.

(ii) *Final payments.* At the end of the plan year, actual gross retiree plan-related prescription drug costs incurred by the insurer (or the retiree), and the allowable costs attributable to the gross costs, are determined for each of the sponsor's qualifying covered retirees and submitted for reconciliation after the end of the plan year as specified in paragraph (b)(4)of this section. The data for the reconciliation can be submitted directly to CMS by the insurer in a manner to be specified by CMS. Upon receiving this data, CMS adjusts the payments made for the relevant plan year in a manner to be specified by CMS.

(c) *Use of information provided.* Officers, employees and contractors of the Department of Health and Human Services, including the Office of Inspector General (OIG), may use information collected under this section only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities, or as otherwise required by law. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(d) *Maintenance of records.* (1) The sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain, and furnish to CMS or the OIG upon request, the records enumerated in paragraph (d)(3) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred for the purposes of audits and other oversight activities conducted by CMS to assure the accuracy of the actuarial attestation and the accuracy of payments.

(2) CMS or the OIG may extend the 6-year retention requirement for the records enumerated in paragraph (d)(3) of this section in the event of an ongoing investigation, litigation, or negotiation involving civil, administrative or criminal liability. In addition, the sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain the records enumerated in paragraph (d)(3) of this section longer than 6 years if it knows or should know that the records are the subject of an ongoing investigation, litigation or negotiation involving civil, administrative or criminal liability.

(3) The records that must be retained are:

(i) Reports and working documents of the actuaries who wrote the attestation submitted in accordance with § 423.884(a).

(ii) All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment made in accordance with § 423.886, including the underlying claims data.

(iii) Any other records specified by CMS.

(4) CMS may issue additional guidance addressing recordkeeping requirements, including (but not limited to) the use of electronic media.

§ 423.890 Appeals.

(a) *Informal written reconsideration.* (1) *Initial determinations.* A sponsor is entitled to an informal written reconsideration of an adverse initial determination. An initial determination is a determination regarding the following:

(i) The amount of the subsidy payment.

(ii) The actuarial equivalence of the sponsor's retiree prescription drug plan.

(iii) If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or

(iv) Any other similar determination (as determined by CMS) that affects eligibility for, or the amount of, a subsidy payment.

(2) *Effect of an initial determination regarding the retiree drug subsidy*. An initial determination is final and binding unless reconsidered in accordance with this paragraph (a) of this section.

(3) *Manner and timing for request*. A request for reconsideration must be made in writing and filed with CMS within 15 days of the date on the notice of adverse determination.

(4) *Content of request*. The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(5) *Conduct of informal written reconsideration*. In conducting the reconsideration, CMS reviews the subsidy determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS before notice of the reconsidered determination is made.

(6) *Decision of the informal written reconsideration*. CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the sponsor on the sponsor's request.

(7) *Effect of CMS informal written reconsideration*. A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (b) of this section, or it is revised in accordance paragraph (d) of this section.

(b) *Right to informal hearing*. A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request*. A request for a hearing must be made in writing and filed with CMS within 15 days of the date the sponsor receives the CMS reconsideration decision.

(2) *Content of request*. The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures*. (i)CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer*. The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) *Effect of hearing officer decision*. The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) *Review by the Administrator*. (1) A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision

and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

(d) *Reopening*. (1) *Ability to reopen*. CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) *Notice of reopening*. (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) *Effect of reopening*. The revision of an initial or reconsidered determination is final and binding unless-

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) *Good cause*. For purposes of this section, CMS finds good cause if—

(i) New and material evidence exists that was not readily available at the time the initial determination was made;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.

(6) A decision by CMS not to reopen an initial or reconsidered determination is final and binding and cannot be appealed.

§ 423.892 Change of ownership.

(a) *Change of ownership*. Any of the following constitutes a change of ownership:

(1) *Partnership*. The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law.

(2) *Asset sale*. Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation*. The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception*. Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement*. A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement*. When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements*. The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

§ 423.894 Construction.

Nothing in this part must be interpreted as prohibiting or restricting:

(a) A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a Part D plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a Part D plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is—

(1) Supplemental to the benefits provided under a Part D plan; or

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(d)); or

(d) Sponsors from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to Part D plans under § 423.104, as long as the requirements under § 423.884 are met.

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions

§ 423.900 Basis and scope.

(a) *Basis.* This subpart is based on sections 1935(a) through (d) of the Act as amended by section 103 of the MMA.

(b) *Scope.* This subpart specifies State agency obligations for the Part D prescription drug benefit.

§ 423.902 Definitions.

The following definitions apply to this subpart:

Actuarial value of capitated prescription drug benefits is the estimated actuarial value of prescription drug benefits provided under a comprehensive Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate. This value will be established using data determined by the Secretary to be the best available among the following options:

(1) State rate setting documentation for drug costs to the full dual eligible population;

(2) State encounter and enrollment record databases including cost data; and

(3) State managed care plan-specific financial cost data; and

(4) Other appropriate data.

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Total Drug National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year, as described in § 423.104(d)(5)(iv). CMS provides further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

Base year Medicaid per capita expenditures are equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and

(2) The estimated actuarial value of prescription drug benefits provided under a comprehensive capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full-benefit dual eligibles with comprehensive managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations reported through the Medicaid Statistical Information System (MSIS).

Full-benefit dual eligible individual means an individual who, for any month-

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus demonstrations or under a section 1115 of the Act demonstration that provides pharmacy only benefits to these individuals.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act

(medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month. For the 2003 baseline calculations, the full-benefit dual eligibles are those individuals reported in MSIS as having Medicaid drug benefit coverage and Medicare Part A or Part B coverage. Dual eligibility status will be established by CMS using an algorithm that incorporates the quarterly MSIS dual eligibility code for the prescription fill date and the dual eligibility code for the prior quarter.

Gross base year Medicaid per capita expenditures are equal to the expenditures, including dispensing fees, made by the State and reported in MSIS during calendar year 2003 for covered outpatient drugs, excluding drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1860D–2 of the Act, other than smoking cessation agents determined per full-benefit dual eligible individual for the individuals not receiving medical assistance for the drugs through a comprehensive Medicaid managed care plan. This amount is determined based on MSIS drug claims paid during the four quarters of calendar year 2003 and the corresponding dual eligibility enrollment status of the beneficiary. MSIS drug claims having National Drug Codes determined by CMS to be in the Part D excluded drug class, and claims having a program type code indicating Indian Health Service or Family Planning will be excluded from the calculation.

Phased-down State contribution factor for a month in 2006 is 90 percent; in 2007 is 88 1/3 percent; in 2008 is 86 2/3 percent; in 2009 is 85 percent; in 2010 is 83 1/3 percent; in 2011 is 81 2/3 percent; in 2012 is 80 percent; in 2013 is 78 1/3 percent; in 2014 is 76 2/3 percent; or after December 2014, is 75 percent.

Phased-down State contribution payment refers to the States' monthly payment made to the Federal government beginning in 2006 to defray a portion of the Medicare drug expenditures for full-benefit dual eligible individuals whose Medicaid drug coverage is assumed by Medicare Part D. The contribution is calculated as 1/12th of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals,

(1) Multiplied by the State medical assistance percentage;

(2) Increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor;

(3) Multiplied by the number of the State's full-benefit dual eligible individuals for the given month; and

(4) Multiplied by the phased-down State contribution factor.

Rebate adjustment factor takes into account drug rebates and, for a State, is equal to the ratio of the four quarters of calendar year 2003 of aggregate rebate payments received by the State under section 1927 of the Act to the gross expenditures for covered outpatient drugs.

State medical assistance percentage means the proportion equal to 100 percent minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs.

§ 423.904 Eligibility determinations for low-income subsidies.

(a) *General rule*. The State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies in accordance with subpart P of part 423.

(b) *Notification to CMS*. The State agency must inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS.

(c) *Screening for eligibility for Medicare cost-sharing and enrollment under the State plan*. States must—

(1) Screen individuals who apply for subsidies under this part for eligibility for Medicaid programs that provide assistance with Medicare cost-sharing specified in section 1905(p)(3) of the Act.

(2) Offer enrollment for the programs under the State plan (or under a waiver of the plan) for those meeting the eligibility requirements.

(d) *Application form and process*. (1) *Assistance with application*. No later

than July 1, 2005, States must make available—

(i) Low-income subsidy application forms;

(ii) Information on the nature of, and eligibility requirements for, the subsidies under this section; and

(iii) Assistance with completion of low-income subsidy application forms.

(2) *Completion of application*. The State must require an individual or personal representative applying for the low-income subsidy to—

(i) Complete all required elements of the application and provide documents, as necessary, consistent with paragraph (d)(3) of this section; and

(ii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(3) *The application process and States*. (i) States may require submission of statements from financial institutions for an application for low-income subsidies to be considered complete; and

(ii) May require that information submitted on the application be subject to verification in a manner the State determines to be most cost-effective and efficient.

(4) *Other information*. States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

§ 423.906 General payment provisions.

(a) *Regular Federal matching*. Regular Federal matching applies to the eligibility determination and notification activities specified in § 423.904(a) and (b).

(b) *Medicare as primary payer*. Medicare is the primary payer for covered drugs for Part D eligible individuals. Medical assistance is not available to full-benefit dual eligible individuals, including those not enrolled in a Part D plan, for—

(1) Covered Part D drugs; or

(2) Any cost-sharing obligations under Part D relating to covered Part D drugs.

(3) The effective date of paragraphs (b)(1) and (b)(2) of this section is January 1, 2006.

(c) *Non-covered drugs*. States may elect to provide coverage for outpatient drugs other than covered Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan.

§ 423.907 Treatment of territories.

(a) *General rules*. (1) Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under subpart P of this part.

(2) A territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs.

(3) Territories with plans approved by the Secretary will receive increased grants under section 1935(e)(3) of the Act as described in paragraph (c) of this section.

(b) *Plan requirements*. Plans submitted to the Secretary must include the following:

(1) A description of the medical assistance to be

provided.

(2) The low-income population (income less than 150

percent of the Federal poverty level) to receive medical assistance.

(3) An assurance that no more than 10 percent of the

amount of the increased grant will be used for administrative expenses.

(c) *Increased grant amounts*. The amount of the grant provided under section 1108 (f) of the Act as increased by section 1108 (g) of the Act for each territory with an approved plan for a year is the amount in paragraph (d) of this section multiplied by the ratio of—

(1) The number of individuals who are entitled to benefits under Part A or enrolled under Part B and who reside in the territory (as determined by the Secretary based on the most recent available data for the beginning of the year); and

(2) The sum of the number of individuals in all territories in paragraph (c)(1) of this section with approved plans.

(d) *Total grant amount.* The total grant amount is—

(1) For the last three quarters of fiscal year 2006, $28,125,000;

(2) For fiscal year 2007, $37,500,000; and

(3) For each subsequent year, the amount for the prior fiscal year increased by the annual percentage increase described in § 423.104(d)(5)(iv).

§ 423.908. Phased-down State contribution to drug benefit costs assumed by Medicare.

This subpart sets forth the requirements for State contributions for Part D drug benefits based on full-benefit dual eligible individual drug expenditures.

§ 423.910 Requirements.

(a) *General rule.* Each of the 50 States and the District of Columbia is required to provide for payment to CMS a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.

(b) *State contribution payment.* (1) *Calculation of payment.* The State contribution payment is calculated by CMS on a monthly basis, as indicated in the following chart. For States that do not meet the quarterly reporting requirement for the monthly enrollment reporting, the State contribution payment is calculated using a methodology determined by CMS.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006

	Item	Illustrative Value	Source
(i)	Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a comprehensive Medicaid managed care plan, excluding drugs not covered by Part D	$2,000	CY MSIS data
(ii)	Aggregate State rebate receipts in calendar year 2003	$100,000,000	CMS–64
(iii)	Gross State Medicaid expenditures for prescription drugs in calendar year 2003	$500,000,000	CMS–64
(iv)	Rebate adjustment factor	0.2000	(2) ÷ (3)
(v)	Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in comprehensive managed care plans	$1,600	(1) x [1- (4)]
(vi)	Estimated actuarial value of prescription drug benefits under comprehensive capitated managed care plans for full-benefit dual eligibles for 2003	$1,500	To be Determined
(vii)	Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through comprehensive Medicaid managed care plans	90,000	CY MSIS data
(viii)	Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through comprehensive Medicaid managed care plans	10,000	CY MSIS data
(ix)	Base year State Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6))	$1,590	[(7)x(5) + (8)x(6)]÷[(7) + (8)]
(x)	100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of State contribution (as a proportion)	0.4000	**Federal Register**
(xi)	Applicable growth factor (cumulative increase from 2003 through 2006)	50.0%	NHE projections

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006—Continued

	Item	Illustrative Value	Source
(xii)	Number of full-benefit dual eligibles for the month	120,000	State submitted data
(xiii)	Phased-down State reduction factor for the month	0.9000	specified in statute
(xiv)	Phased-down State contribution for the month	$8,586,000	1/12 x (9) x (10) x [1+(11)] x (12) x (13)

(2) *Method of payment*. Payments for the phased down State contribution begins in January 2006, and are made on a monthly basis for each subsequent month. State payment must be made in a manner specified by CMS that is similar to the manner in which State payments are made under the State Buy-in Program except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. The policy on collection of the Phased-down State contribution payment is the same as the policy that governs collection of Part A and Part B Medicare premiums for State Buy-in.

(c) *State Medicaid Statistical Information System (MSIS) Reporting*. Effective with calendar year (CY) 2003 and all subsequent MSIS data submittals, States are required to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles. Calendar year 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004.

(d) *State monthly enrollment reporting*. Effective June 2005, and each subsequent month, States must submit an electronic file, in a manner specified by CMS, identifying each full-benefit dual eligible individual enrolled in the State for each month. This file must include specified information including identifying information, a dual eligible type code, available income data and institutional status. The file includes data on enrollment for the current month, plus retroactive changes in enrollment characteristics for prior months. This file will be used by CMS to establish the monthly enrollment for those individuals with Part D drug coverage who are also determined by the State to be eligible for full Medicaid benefits subject to the phased down State contribution payment. This file is due to CMS no later than the last day of the reporting month. For States that do not submit an acceptable file by the end of the month, the phased down State contribution for that month is based on data deemed appropriate by CMS.

(e) *Data match*. CMS performs those periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment.

(f) *Rebate adjustment factor*. CMS establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004. Rebates include rebates received under the national rebate agreement and under a State supplemental rebate program, as reported on CMS–64 expenditure reports for the four quarters of calendar year 2003.

(g) *Annual per capita drug expenditures*. CMS notifies each State no later than October 15 before each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 53 FR 6634, Mar. 2, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 424.1 Basis and scope.

(a) *Statutory basis.* (1) This part is based on the indicated provisions of the following sections of the Act:

1814—Basic conditions for, and limitations on, Medicare payments for Part A services.
1815—Payment to providers for Part A services.
1820—Conditions for designating certain hospitals as critical assess hospitals.
1835—Procedures for payment to providers for Part B services.
1842(b)(3)(B)(ii)—Assignment of Part B Medicare claims.
1842(b)(6)—Payment to entities other than the supplier.
1848—Payment for physician services.
1870(e) and (f)—Settlement of claims after death of the beneficiary.

(2) Section 424.444(c) is also based on section 216(j) of the Act.

(b) *Scope.* This part sets forth certain specific conditions and limitations applicable to Medicare payments and cites other conditions and limitations set forth elsewhere in this chapter. This subpart A provides a general overview. Other subparts deal specifically with—

(1) The requirement that the need for services be certified and that a physician establish a plan of treatment (subpart B);

(2) The procedures and time limits for filing claims (subpart C);

(3) The individuals or entities to whom payment may be made (subparts D and E);

(4) The limitations on assignment and reassignment of claims (subpart F);

(5) Special requirements that apply to services furnished by nonparticipating U.S. hospitals and foreign hospitals (subparts G and H); and

(6) The replacement and reclamation of Medicare payment checks (subpart M).

(c) *Other applicable rules.* Except for § 424.40(c)(3), this part does not deal with the conditions for payment of rural health clinic (RHC) services, Federally qualified health center (FQHC) services, or ambulatory surgical center (ASC) services. Those conditions are set forth in part 405, subpart X, and part 481 subpart A of this chapter for RHC and FQHC services; and in part 416 of this chapter, for ASC services. The rules for physician certification of terminal illness, required in connection with hospice care, are set forth in § 418.22 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 60 FR 38271, July 26, 1995; 60 FR 50442, Sept. 29, 1995; 62 FR 46035, Aug. 29, 1997]

§ 424.3 Definitions.

As used in this part, unless the context indicates otherwise—

HCPCS means Healthcare Common Procedure Coding System.

ICD–9–CM means International Classification of Diseases, Ninth Revision, Clinical Modification.

Nonparticipating hospital means a hospital that does not have in effect a provider agreement to participate in Medicare.

Participating hospital means a hospital that has in effect a provider agreement to participate in Medicare.

[53 FR 6634, Mar. 2, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 63 FR 26311, May 12, 1998; 70 FR 45055, Aug. 4, 2005]

§ 424.5 Basic conditions.

(a) As a basis for Medicare payment, the following conditions must be met:

(1) *Types of services.* The services must be—

(i) Covered services, as specified in part 409 or part 410 of this chapter; or

(ii) Services excluded from coverage as custodial care or services not reasonable and necessary, but reimbursable in accordance with §§ 405.332 through 405.334 of this chapter, pertaining to limitation of liability.

(2) *Sources of services.* The services must have been furnished by a provider, nonparticipating hospital, or

supplier that was, at the time it furnished the services, qualified to have payment made for them.

(3) *Recipient of services*. Except as provided in § 409.68 of this chapter, the services must have been furnished while the individual was eligible to have payment made for them. (Section 409.68 provides for payment of inpatient hospital services furnished before the hospital is notified that the beneficiary has exhausted the Medicare benefits available for the current benefit period.)

(4) *Certification of need for services*. When required, the provider must obtain certification and recertification of the need for the services in accordance with subpart B of this part.

(5) *Claim for payment*. The provider, supplier, or beneficiary, as appropriate, must file a claim that includes or makes reference to a request for payment, in accordance with subpart C of this part.

(6) *Sufficient information*. The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment.

(b) Additional conditions applicable in certain circumstances or to certain services are set forth in other sections of this part.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 60 FR 38271, July 26, 1995]

§ 424.7 General limitations.

(a) *Utilization review finding on medical necessity*. When a QIO or a UR committee notifies a hospital or SNF of its finding that further services are not medically necessary, the following rules apply:

(1) *Hospitals subject to PPS*. Payment may not be made for inpatient hospital services furnished by a PPS hospital after the second day after the day on which the hospital received the notice.

(2) *Hospitals not subject to PPS and SNFs*—(i) *Basic rule*. Except as provided in paragraph (a)(2)(ii) of this section, payment may not be made for inpatient hospital services or posthospital SNF care furnished after the day on which the hospital or SNF received the notice.

(ii) *Exception*. Payment may be made for 1 or 2 additional days if the QIO or UR committee approves them as necessary for planning for post-discharge care.

(b) *Failure to make timely utilization review*. Payment may not be made for inpatient hospital services or posthospital SNF care furnished, after the 20th consecutive day of a stay, to an individual who is admitted to the hospital or SNF after CMS has determined that the hospital or SNF has failed to make timely utilization review in long stay cases. (This provision does not apply to a hospital or SNF for which a QIO has assumed binding review.)

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

Subpart B—Certification and Plan of Treatment Requirements

§ 424.10 Purpose and scope.

(a) *Purpose*. The physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs, and treatments, and determines the length of stay. Accordingly, sections 1814(a)(2) and 1835(a)(2) of the Act establish as a condition for Medicare payment that a physician certify the necessity of the services and, in some instances, recertify the continued need for those services.

Section 1814(a)(2) of the Act also permits nurse practitioners or clinical nurse specialists to certify and recertify the need for post-hospital extended care services.

(b) *Scope*. This subpart sets forth the timing, content, and signature requirements for certification and recertification with respect to certain Medicare services furnished by providers.

[60 FR 38271, July 26, 1995]

§ 424.11 General procedures.

(a) *Responsibility of the provider*. The provider must—

(1) Obtain the required certification and recertification statements;

(2) Keep them on file for verification by the intermediary, if necessary; and

(3) Certify, on the appropriate billing form, that the statements have been obtained and are on file.

(b) *Obtaining the certification and recertification statements.* No specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form. Except as provided in paragraph (d) of this section for delayed certifications, there must be a separate signed statement for each certification or recertification.

(c) *Required information.* The succeeding sections of this subpart set forth specific information required for different types of services. If that information is contained in other provider records, such as physicians' progress notes, it need not be repeated. It will suffice for the statement to indicate where the information is to be found.

(d) *Timeliness.* (1) The succeeding sections of this subpart also specify the time frames for certifications and for initial and subsequent recertifications.

(2) A hospital or SNF may provide for obtaining a certification or recertification earlier than required by these regulations, or vary the time frame (within the prescribed outer limits) for different diagnostic or clinical categories.

(3) Delayed certification and recertification statements are acceptable when there is a legitimate reason for delay. (For instance, the patient was unaware of his or her entitlement when he or she was treated.) Delayed certification and recertification statements must include an explanation of the reason for the delay.

(4) A delayed certification may be included with one or more recertifications on a single signed statement.

(e) *Limitation on authorization to sign statements.* A certification or recertification statement may be signed only by one of the following:

(1) A physician who is a doctor of medicine or osteopathy.

(2) A dentist in the circumstances specified in § 424.13(c).

(3) A doctor of podiatric medicine if his or her certification is consistent with the functions he or she is authorized to perform under State law.

(4) A nurse practitioner or clinical nurse specialist, as defined in paragraph (e)(5) or (e)(6) of this section, in the circumstances specified in § 424.20(e).

(5) For purposes of this section, to qualify as a nurse practitioner, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a nurse practitioner in accordance with State law; and have a master's degree in nursing;

(ii) Be certified as a nurse practitioner by a professional association recognized by CMS that has, at a minimum, eligibility requirements that meet the standards in paragraph (e)(5)(i) of this section; or

(iii) Meet the requirements for a nurse practitioner set forth in paragraph (e)(5)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

(6) For purposes of this section, to qualify as a clinical nurse specialist, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a clinical nurse specialist in accordance with State law; and have a master's degree in a defined clinical area of nursing;

(ii) Be certified as a clinical nurse specialist by a professional association recognized by CMS that has at a minimum, eligibility requirements that meet the standards in paragraph (e)(6)(i) of this section; or

(iii) Meet the requirements for a clinical nurse specialist set forth in paragraph (e)(6)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal

advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

[53 FR 6634, Mar. 2, 1988, as amended at 56 FR 8845, Mar. 1, 1991; 60 FR 38272, July 26, 1995]

§ 424.13 Requirements for inpatient services of hospitals other than psychiatric hospitals.

(a) *Content of certification and recertification.* Medicare Part A pays for inpatient hospital services of hospitals other than psychiatric hospitals only if a physician certifies and recertifies the following:

(1) The reasons for either—

(i) Continued hospitalization of the patient for medical treatment or medically required inpatient diagnostic study; or

(ii) Special or unusual services for cost outlier cases (under the prospective payment system set forth in subpart F of part 412 of this chapter).

(2) The estimated time the patient will need to remain in the hospital.

(3) The plans for posthospital care, if appropriate.

(b) *Certification of need for hospitalization when a SNF bed is not available.* (1) A physician may certify or recertify need for continued hospitalization if the physician finds that the patient could receive proper treatment in a SNF but no bed is available in a participating SNF.

(2) If this is the basis for the physician's certification or recertification, the required statement must so indicate; and the physician is expected to continue efforts to place the patient in a participating SNF as soon as a bed becomes available.

(c) *Signatures.* (1) *Basic rule.* Except as specified in paragraph (c)(2) of this section, certifications and recertifications must be signed by the physician responsible for the case, or by another physician who has knowledge of the case and who is authorized to do so by the responsible physician or by the hospital's medical staff.

(2) *Exception.* If the intermediary requests certification of the need to admit a patient in connection with dental procedures, because his or her underlying medical condition and clinical status or the severity of the dental procedures require hospitalization, that certification may be signed by the dentist caring for the patient.

(d) *Timing of certifications and recertifications: Cases not subject to the prospective payment system* (PPS). (1) For cases that are not subject to PPS, certification is required no later than as of the 12th day of hospitalization. A hospital may, at its option, provide for the certification to be made earlier, or it may vary the timing of the certification within the 12-day period by diagnostic or clinical categories.

(2) The first recertification is required no later than as of the 18th day of hospitalization.

(3) Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(e) *Timing of certification and recertification: Cases subject to PPS.* For cases subject to PPS, certification is required as follows:

(1) For day-outlier cases, certification is required no later than one day after the hospital reasonably assumes that the case meets the outlier criteria, established in accordance with § 412.80(a)(1)(i) of this chapter, or no later than 20 days into the hospital stay, whichever is earlier. The first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses) but not less frequently than every 30 days.

(2) For cost-outlier cases, certification is required no later than the date on which the hospital requests cost outlier payment or 20 days into the hospital stay, whichever is earlier. If possible, certification must be made before the hospital incurs costs for which it will seek cost outlier payment. In cost outlier cases, the first and subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses).

(f) *Recertification requirement fulfilled by utilization review.* (1) At the hospital's option, extended stay review by its UR committee may take the place of the second and subsequent physician recertifications required for cases not

subject to PPS and for PPS day-outlier cases.

(2) A utilization review that is used to fulfill the recertification requirement is considered timely if performed no later than the seventh day after the day the physician recertification would have been required. The next physician recertification would need to be made no later than the 30th day following such review; if review by the UR committee took the place of this physician recertification, the review could be performed as late as the seventh day following the 30th day.

(g) *Description of procedures.* The hospital must have available on file a written description that specifies the time schedule for certifications and recertifications, and indicates whether utilization review of long-stay cases fulfills the requirement for second and subsequent recertifications of all cases not subject to PPS and of PPS day outlier cases.

§ 424.14 Requirements for inpatient services of psychiatric hospitals.

(a) *Content of certification and recertification: General considerations.* The content requirements differ from those for other hospitals because the care furnished in psychiatric hospitals is often purely custodial and thus not covered under Medicare. The purpose of the statements, therefore, is to help ensure that Medicare pays only for services of the type appropriate for Medicare coverage. Accordingly, Medicare Part A pays for inpatient care in a psychiatric hospital only if a physician certifies and recertifies the need for services consistent with the content of paragraphs (b) or (c) of this section, as appropriate.

(b) *Content of certification.* Inpatient psychiatric services were required—

(1) For treatment that could reasonably be expected to improve the patient's condition; or

(2) For diagnostic study.

(c) *Content of recertification.* (1) Inpatient services furnished since the previous certification or recertification were, and continue to be, required—

(i) For treatment that could reasonably be expected to improve the patient's condition; or

(ii) For diagnostic study; and

(2) The hospital records show that the services furnished were—

(i) Intensive treatment services;

(ii) Admission and related services necessary for diagnostic study; or

(iii) Equivalent services.

(d) *Timing of certification and recertification.* (1) Certification is required at the time of admission or as soon thereafter as is reasonable and practicable.

(2) The first recertification is required as of the 18th day of hospitalization. Subsequent recertifications are required at intervals established by the UR committee (on a case-by-case basis if it so chooses), but no less frequently than every 30 days.

(e) *Other requirements.* Psychiatric hospitals must also meet the requirements set forth in § 424.13 (b), (c), (f), and (g).

§ 424.15 Requirements for inpatient CAH services.

(a) *Content of certification.* Medicare Part A pays for inpatient CAH services only if a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH.

(b) *Timing of certification.* Certification is required no later than 1 day before the date on which the claim for payment for the inpatient CAH services is submitted.

[58 FR 30671, May 26, 1993, as amended at 60 FR 45850, Sept. 1, 1995; 62 FR 46035, 46037, Aug. 29, 1997]

§ 424.16 Timing of certification for individual admitted to a hospital before entitlement to Medicare benefits.

(a) *Basic rule.* If an indivdual is admitted to a hospital before becoming entitled to Medicare benefits (for instance, before attaining age 65), the day of entitlement (instead of the day of admission) is the starting point for the time limits specified in § 424.13(e) for certification and recertification.

(b) *Example. (Hospital that is not a psychiatric hospital and is not subject to PPS).* For a patient who is admitted on August 15 and becomes entitled on September 1—

(1) The certification is required no later than September 12;

(2) The first recertification is required no later than September 18; and

(3) Subsequent recertifications are required at least every 30 days after September 18.

[53 FR 6635, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.20 Requirements for posthospital SNF care.

Medicare Part A pays for posthospital SNF care furnished by an SNF, or a hospital or CAH with a swing-bed approval, only if the certification and recertification for services are consistent with the content of paragraph (a) or (c) of this section, as appropriate.

(a) *Content of certification*—(1) *General requirements*. Posthospital SNF care is or was required because—

(i) The individual needs or needed on a daily basis skilled nursing care (furnished directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in an SNF or a swing-bed hospital on an inpatient basis, and the SNF care is or was needed for a condition for which the individual received inpatient care in a participating hospital or a qualified hospital, as defined in § 409.3 of this chapter; or

(ii) The individual has been correctly assigned to one of the Resource Utilization Groups designated as representing the required level of care, as provided in § 409.30 of this chapter.

(2) *Special requirement for certifications performed prior to July 1, 2002: A swing-bed hospital with more than 49 beds (but fewer than 100) that does not transfer a swing-bed patient to a SNF within 5 days of the availability date*. Transfer of the extended care patient to the SNF is not medically appropriate.

(b) *Timing of certification*. (1) *General rule*. The certification must be obtained at the time of admission or as soon thereafter as is reasonable and practicable.

(2) *Special rules for certain swing-bed hospitals*. For swing-bed hospitals with more than 49 beds that are approved after March 31, 1988, the extended care patient's physician has 5 days (excluding weekends and holidays) beginning on the availability date as defined in § 413.114(b), to certify that the transfer of the extended care patient is not medically appropriate.

(c) *Content of recertifications*. (1) The reasons for the continued need for posthopsital SNF care:

(2) The estimated time the individual will need to remain in the SNF;

(3) Plans for home care, if any; and

(4) If appropriate, the fact that continued services are needed for a condition that arose after admission to the SNF and while the individual was still under treatment for the condition for which he or she had received inpatient hospital services.

(d) *Timing of recertifications*. (1) The first recertification is required no later than the 14th day of posthospital SNF care.

(2) Subsequent recertifications are required at least every 30 days after the first recertification.

(e) *Signature*. Certification and recertification statements may be signed by—

(1) The physician responsible for the case or, with his or her authorization, by a physician on the SNF staff or a physician who is available in case of an emergency and has knowledge of the case; or

(2) A nurse practitioner or clinical nurse specialist, neither of whom has a direct or indirect employment relationship with the facility but who is working in collaboration with a physician. For purposes of this section—

(i) *Collaboration* means a process whereby a nurse practitioner or clinical nurse specialist works with a doctor of medicine or osteopathy to deliver health care services. The services are delivered within the scope of the nurse's professional expertise, with medical direction and appropriate supervision as provided for in guidelines jointly developed by the nurse and the physician or other mechanisms defined by Federal regulations and the law of the State in which the services are performed.

(ii) A *direct employment relationship* with the facility is one in which the nurse practitioner or clinical nurse specialist meets the common law definition of the facility's ''employee,'' as specified in § 404.1005, § 404.1007, and § 404.1009 of title 20 of the regulations.

When a nurse practitioner or clinical nurse specialist meets this definition with respect to an entity other than the facility itself, and that entity has an agreement with the facility for the provision of nursing services under § 409.21 of this subchapter, the facility is considered to have an *indirect employment relationship* with the nurse practitioner or clinical nurse specialist. An indirect employment relationship does not exist if the agreement between the entity and the facility involves only the performance of delegated physician tasks under § 483.40(e) of this chapter.

(f) *Recertification requirement fulfilled by utilization review.* A SNF may substitute utilization review of extended stay cases for the second and subsequent recertifications, if it includes this procedure in its utilization review plan.

(g) *Description of procedures.* The SNF must have available on file a written description that specifies the certification and recertification time schedule and indicates whether utilization review is used as an alternative to the second and subsequent recertifications.

[53 FR 6634, Mar. 2, 1988, as amended at 54 FR 37275, Sept. 7, 1989; 58 FR 30671, May 26, 1993; 60 FR 38272, July 26, 1995; 62 FR 46037, Aug. 29, 1997; 63 FR 26311, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 66 FR 39600, July 31, 2001; 70 FR 45055, Aug. 4, 2005]

§ 424.22 Requirements for home health services.

Medicare Part A or Part B pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) *Certification*—(1) *Content of certification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify as follows:

(i) The individual needs or needed intermittent skilled nursing care, or physical or speech therapy, or (for the period from July through November 30, 1981) occupational therapy.

(ii) Home health services were required because the individual was confined to the home except when receiving outpatient services.

(iii) A plan for furnishing the services has been established and is periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

(iv) The services were furnished while the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.[1]

(2) *Timing and signature.* The certification of need for home health services must be obtained at the time the plan of treatment is established or as soon thereafter as possible and must be signed by the physician who establishes the plan.

(b) *Recertification.* (1) *Timing and signature of recertification.* Recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed by the physician who reviews the plan of care. The recertification is required at least every 60 days when there is a—

(i) Beneficiary elected transfer; or

(ii) Discharge and return to the same HHA during the 60-day episode.

(2) *Content and basis of recertification.* The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical or speech therapy.

(c) [Reserved]

(d) *Limitation on the performance of certification and plan of treatment functions.* The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of treatment may not be established and reviewed, by any physician who has a financial relationship, as defined in § 411.351 of this chapter, with that HHA,

[1] As a condition of Medicare Part A payment for home health services furnished before July 1981, the physician was also required to certify that the services were needed for a condition for which the individual had received inpatient hosptial or SNF services.

unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, Mar. 1, 1991, as amended at 65 FR 41211, July 3, 2000; 66 FR 962, Jan. 4, 2001]

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

(a) *Exempted services.* Certification is not required for the following: (1) Hospital services and supplies incident to physicians' services furnished to outpatients. The exemption applies to drugs and biologicals that cannot be self-administered, but not to partial hospitalization services, as set forth in paragraph (e) of this section.

(2) Outpatient hospital diagnostic services, including necessary drugs and biologicals, ordinarily furnished or arranged for by a hospital for the purpose of diagnostic study.

(b) *General rule.* Medicare Part B pays for medical and other health services furnished by providers (and not exempted under paragraph (a) of this section) only if a physician certifies the content specified in paragraph (c)(1), (c)(4) or (e)(1) of this section, as appropriate.

(c) *Outpatient physical therapy and speech-language pathology services*—(1) *Content of certification.* (i) The individual needs, or needed, physical therapy or speech pathology services.

(ii) The services were furnished while the individual was under the care of a physician, nurse practitioner, clinical nurse specialist, or physician assistant.

(iii) The services were furnished under a plan of treatment that meets the requirements of § 410.61 of this chapter.

(2) *Timing.* The certification statement must be obtained at the time the plan of treatment is established, or as soon thereafter as possible.

(3) *Signature.* (i) If the plan of treatment is established by a physician, nurse practitioner, clinical nurse specialist, or physician assistant, the certification must be signed by that physician or nonphysician practitioner.

(ii) If the plan of treatment is established by a physical therapist or speech-language pathologist, the certification must be signed by a physician or by a nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(4) *Recertification*—(i) *Timing.* Recertification statements are required at least every 30 days and must be signed by the physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan of treatment.

(ii) *Content.* The recertification statement must indicate the continuing need for physical therapy or speech-language pathology services and an estimate of how much longer the services will be needed.

(iii) *Signature.* Recertifications must be signed by the physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan of treatment.

(d) [Reserved]

(e) *Partial hospitalization services: Content of certification and plan of treatment requirements*—(1) *Content of certification.* (i) The individual would require inpatient psychiatric care if the partial hospitalization services were not provided.

(ii) The services are or were furnished while the individual was under the care of a physician.

(iii) The services were furnished under a written plan of treatment that meets the requirements of paragraph (e)(2) of this section.

(2) *Plan of treatment requirements.* (i) The plan is an individualized plan that is established and is periodically reviewed by a physician in consultation with appropriate staff participating in the program, and that sets forth—

(A) The physician's diagnosis;

(B) The type, amount, duration, and frequency of the services; and

(C) The treatment goals under the plan.

(ii) The physician determines the frequency and duration of the services taking into account accepted norms of

medical practice and a reasonable expectation of improvement in the patient's condition.

(3) *Recertification requirements.*

(i) *Signature.* The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.

(ii) *Timing.* The first recertification is required as of the 18th day of partial hospitalization services. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days.

(iii) *Content.* The recertification must specify that the patient would otherwise require inpatient psychiatric care in the absence of continued stay in the partial hospitalization program and describe the following:

(A) The patient's response to the therapeutic interventions provided by the partial hospitalization program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the partial hospitalization program.

(f) *All other covered medical and other health services furnished by providers*—(1) *Content of certification.* The services were medically necessary,

(2) *Signature.* The certificate must be signed by a physician, nurse practioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(3) *Timing.* The physician, nurse practioner, clinical nurse specialist, or physician assistant may provide certification at the time the services are furnished or, if services are provided on a continuing basis, either at the beginning or at the end of a series of visits.

(4) *Recertification.* Recertification of continued need for services is not required.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, 8853, Mar. 1, 1991; 63 FR 58912, Nov. 2, 1998; 65 FR 18548, Apr. 7, 2000]

§ 424.27 Requirements for comprehensive outpatient rehabilitation facility (CORF) services.

Medicare Part B pays for CORF services only if a physician certifies, and the facility physician recertifies, the content specified in paragraphs (a) and (b)(2) of this section, as appropriate.

(a) *Certification: Content.* (1) The services were required because the individual needed skilled rehabilitation services;

(2) The services were furnished while the individual was under the care of a physician; and

(3) A written plan of treatment has been established and is reviewed periodically by a physician.

(b) *Recertification*—(1) *Timing.* Recertification is required at least every 60 days, based on review by a facility physician who, when appropriate, consults with the professional personnel who furnish the services.

(2) *Content.* (i) The plan is being followed;

(ii) The patient is making progress in attaining the rehabilitation goals; and,

(iii) The treatment is not having any harmful effect on the patient.

Subpart C—Claims for Payment

§ 424.30 Scope.

This subpart sets forth the requirements, procedures, and time limits for claiming Medicare payments. Claims must be filed in all cases except when services are furnished on a prepaid capitation basis by a health maintenance organization (HMO), a competitive medical plan (CMP), or a health care prepayment plan (HCPP). Special procedures for claiming payment after the beneficiary has died and for certain bills paid by organizations are set forth in subpart E of this part.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.32 Basic requirements for all claims.

(a) A claim must meet the following requirements:

(1) A claim must be filed with the appropriate intermediary or carrier on a form prescribed by CMS in accordance with CMS instructions.

(2) A claim for physician services, clinical psychologist services, or clinical social worker services must include appropriate diagnostic coding for those services using ICD–9–CM.

(3) A claim must be signed by the beneficiary or the beneficiary's representative (in accordance with § 424.36(b)).

(4) A claim must be filed within the time limits specified in § 424.44.

(5) All Part B claims for services furnished to SNF residents (whether filed by the SNF or by another entity) must include the SNF's Medicare provider number and appropriate HCPCS coding.

(b) The prescribed forms for claims are the following:

CMS–1450—Uniform Institutional Provider Bill. (This form is for institutional provider billing for Medicare inpatient, outpatient and home health services.)

CMS–1490S—Request for Medicare payment. (For use by a patient to request payment for medical expenses.)

CMS–1490U—Request for Medicare Payment by Organization. (For use by an organization requesting payment for medical services.)

CMS–1491—Request for Medicare Payment-Ambulance. (For use by an organization requesting payment for ambulance services.)

CMS–1500—Health Insurance Claim Form. (For use by physicians and other suppliers to request payment for medical services.)

CMS–1660—Request for Information-Medicare Payment for Services to a Patient now Deceased. (For use in requesting amounts payable under title XVIII to a deceased beneficiary.)

(c) *Where claims forms are available.* Excluding forms CMS–1450 and CMS–1500, all claims forms prescribed for use in the Medicare program are distributed free-of-charge to the public, institutions, or organizations. The CMS–1450 and CMS–1500 may be obtained only by commercial purchase. All other claims forms can be obtained upon request from CMS or any Social Security branch or district office, or from Medicare intermediaries or carriers. The CMS–1490S is also available at local Social Security Offices.

(d) *Submission of electronic claims.* (1) *Definitions.* For purposes of this paragraph, the following terms have the following meanings:

(i) *Claim* means a transaction defined at 45 CFR 162.1101(a).

(ii) *Electronic claim* means a claim that is submitted via electronic media. A claim submitted via direct data entry is considered to be an electronic claim.

(iii) *Direct data entry* is defined at 45 CFR 162.103.

(iv) *Electronic media* is defined at 45 CFR 160.103.

(v) *Initial Medicare claim* means a claim submitted to Medicare for payment under Part A or Part B of the Medicare Program under title XVIII of the Act for the first time for processing, including claims sent to Medicare for the first time for secondary payment purposes. *Initial Medicare claim* excludes any adjustment or appeal of a previously submitted claim, and claims submitted for payment under Part C of the Medicare program under Title XVIII of the Act.

(vi) *Physician, practitioner, facility, or supplier* is a Medicare provider other than a *provider of services.*

(vii) *Provider of services* means a provider of services as defined in section 1861(u) of the Act.

(viii) *Small provider of services or small supplier* means—

(A) A provider of services with fewer than 25 full-time equivalent employees; or

(B) A physician, practitioner, facility, or supplier with fewer than 10 full-time equivalent employees.

(2) *Submission of electronic claims required.* Except for claims to which paragraph (d)(3) or (d)(4) of this section applies, an initial Medicare claim may be paid only if submitted as an electronic claim for processing by the Medicare fiscal intermediary or carrier that serves the physician, practitioner, facility, supplier, or provider of services. This requirement does not apply to any other transactions, including adjustment or appeal of the initial Medicare claim.

(3) *Exceptions to requirement to submit electronic claims.* The requirement of paragraph (d)(2) of this section is waived for any initial Medicare claim when—

(i) There is no method available for the submission of an electronic claim. This exception includes claims submitted by Medicare beneficiaries and situations in which the standard adopted by the Secretary at 45 FR 162.1102 does not support all of the information necessary for payment of the claim. The Secretary may identify situations

coming within this exception in guidance.

(ii) The entity submitting the claim is a small provider or small supplier.

(4) *Unusual circumstances.* The Secretary may waive the requirement of paragraph (d)(2) of this section in such unusual circumstances as the Secretary finds appropriate. Unusual circumstances are deemed to exist in the following situations:

(i) The submission of dental claims.

(ii) There is a service interruption in the mode of submitting the electronic claim that is outside the control of the entity submitting the claim, for the period of the interruption.

(iii) On demonstration, satisfactory to the Secretary, of other extraordinary circumstances precluding submission of electronic claims.

(5) *Effective date.* This paragraph (d) is effective October 16, 2003, and applies to claims submitted on or after October 16, 2003.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 63 FR 26311, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 66 FR 39601, July 31, 2001; 68 FR 48813, Aug. 15, 2003]

§ 424.33 Additional requirements: Claims for services of providers and claims by suppliers and nonparticipating hospitals.

All claims for services of providers and all claims by suppliers and nonparticipating hospitals must be—

(a) Filed by the provider, supplier, or hospital; and

(b) Signed by the provider, supplier, or hospital unless CMS instructions waive this requirement.

§ 424.34 Additional requirements: Beneficiary's claim for direct payment.

(a) *Basic rule.* A beneficiary's claim for direct payment for services furnished by a supplier, or by a nonparticipating hospital that has not elected to claim payment for emergency services, must include an itemized bill or a ''report of services'', as specified in paragraphs (b) and (c) of this section.

(b) *Itemized bill from the hospital or supplier.* The itemized bill for the services, which may be receipted or unpaid, must include all of the following information:

(1) The name and address of—

(i) The beneficiary;

(ii) The supplier or nonparticipating hospital that furnished the services; and

(iii) The physician who prescribed the services if they were furnished by a supplier other than the physician.

(2) The place where each service was furnished, e.g., home, office, independent laboratory, hospital.

(3) The date each service was furnished.

(4) A listing of the services in sufficient detail to permit determination of payment under the fee schedule for physicians' services; for itemized bills from physicians, appropriate diagnostic coding using ICD–9–CM must be used.

(5) The charges for each service.

(c) *Report of services furnished by a supplier.* For Medicare Part B services furnished by a supplier, the beneficiary claims may include the ''Report of Services'' portion of the appropriate claims form, completed by the supplier in accordance with CMS instructions, in lieu of an itemized bill.

[53 FR 6634, Mar. 2, 1988, as amended at 59 FR 10299, Mar. 4, 1994; 59 FR 26740, May 24, 1994]

§ 424.36 Signature requirements.

(a) *General rule.* The beneficiary's own signature is required on the claim unless the beneficiary has died or the provisions of paragraph (b), (c), or (d) of this section apply.

(b) *Who may sign when the beneficiary is incapable.* If the beneficiary is physically or mentally incapable of signing the claim, the claim may be signed on his or her behalf by one of the following:

(1) The beneficiary's legal guardian.

(2) A relative or other person who receives social security or other governmental benefits on the beneficiary's behalf.

(3) A relative or other person who arranges for the beneficiary's treatment or exercises other responsibility for his or her affairs.

(4) A representative of an agency or institution that did not furnish the services for which payment is claimed

but furnished other care, services, or assistance to the beneficiary.

(5) A representative of the provider or of the nonparticipating hospital claiming payment for services it has furnished if the provider or nonparticipating hospital is unable to have the claim signed in accordance with paragraph (b) (1), (2), (3), or (4) of this section.

(c) *Who may sign if the beneficiary was not present for the service.* If a provider, nonparticipating hospital, or supplier files a claim for services that involved no personal contact between the provider, hospital, or supplier and the beneficiary (for example, a physician sent a blood sample to the provider for diagnostic tests), a representative of the provider, hospital, or supplier may sign the claim on the beneficiary's behalf.

(d) *Claims by entities that provide coverage complementary to Medicare.* A claim by an entity that provides coverage complementary to Medicare Part B may be signed by the entity on the beneficiary's behalf.

(e) *Acceptance of other signatures for good cause.* If good cause is shown, CMS may honor a claim signed by a party other than those specified in paragraphs (a) through (c) of this section.

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.37 Evidence of authority to sign on behalf of the beneficiary.

(a) *Beneficiary incapable.* When a party specified in § 424.36(b) signs a claim or request for payment statement, he or she must also submit a brief statement that—

(1) Describes his or her relationship to the beneficiary; and

(2) Explains the circumstances that make it impractical for the beneficiary to sign the claim or statement.

(b) *Beneficiary not present for services.* When a representative of the provider, nonparticipating hospital, or supplier signs a claim or request for payment statement under § 424.36(c), he or she must explain why it was not possible to obtain the beneficiary's signature. (For example: ''Patient not physically present for test.'')

[53 FR 6640, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.40 Request for payment effective for more than one claim.

(a) *Basic procedure.* A separate request for payment statement prescribed by CMS and signed by the beneficiary (or by his or her representative) may be included in claims by reference, in the circumstances specified in paragraphs (b) through (d) of this section.

(b) *Claims filed by a provider or nonparticipating hospital*—(1) *Inpatient services.* A signed request for payment statement, included in the first claim for Part A services furnished by a facility (a participating hospital or SNF, or a nonparticipating hospital that has elected to claim payment) during a beneficiary's period of confinement, may be effective for all claims for Part A services the facility furnishes that beneficiary during that confinement.

(2) *Home health services and outpatient physical therapy or speech pathology services.* A signed request for payment statement, included in the first claim for home health services or outpatient physical therapy or speech pathology services furnished by a provider under a plan of treatment, may be effective for all claims for home health services or outpatient physical therapy or speech pathology services furnished by the provider under that plan of treatment.

(c) *Signed statement in the provider record*—(1) *Services to inpatients.* A signed request for payment statement in the files of a participating hospital or SNF may be effective for all claims for services furnished to the beneficiary during a single inpatient stay in that facility—

(i) By the hospital or SNF;

(ii) By physicians, if their services are billed by the hospital or SNF in its name; or

(iii) By physicians who bill separately, if the services were furnished in the hospital or SNF.

(2) *Services to outpatients: Providers and renal dialysis facilities.* A signed request for payment statement retained in the provider's or facility's files may be effective indefinitely, for all claims for services furnished to that beneficiary on an outpatient basis—

(i) By the provider or facility;

(ii) By physicians whose services are billed by the provider or facility in its name; or

(iii) By physicians who bill separately, if the services were furnished in the provider or facility.

(3) *Services to outpatients: Independent rural health clinics and Federally qualified health centers.* A signed request for payment statement retained in the clinic's or center's files may be effective indefinitely for all claims for services furnished to that beneficiary by the clinic.

(d) *Signed statement in the supplier's record.* A signed request for payment statement retained in the supplier's file may be effective indefinitely subject to the following restrictions:

(1) This policy does not apply to unassigned claims for rental of durable medical equipment (DME).

(2) With respect to assigned claims for rental or purchase of DME, a new statement is required if another item of equipment is rented or purchased.

[53 FR 6634, Mar. 2, 1988, as amended at 57 FR 24982, June 12, 1992]

§ 424.44 Time limits for filing claims.

(a) *Basic limits.* Except as provided in paragraph (b) of this section, the claim must be mailed or delivered to the intermediary or carrier, as appropriate—

(1) On or before December 31 of the following year for services that were furnished during the first 9 months of a calendar year; and

(2) On or before December 31 of the second following year for services that were furnished during the last 3 months of the calendar year.

(b) *Extension of filing time because of error or misrepresentation.* (1) The time for filing a claim will be extended if failure to meet the deadline in paragraph (a) of this section was caused by error or misrepresentation of an employee, intermediary, carrier, or agent of the Department that was performing Medicare functions and acting within the scope of its authority.

(2) The time will be extended through the last day of the 6th calendar month following the month in which the error or misrepresentation is corrected.

(c) *Extension of period ending on a nonworkday.* If the last day of the period allowed under paragraph (a) or (b) of this section falls on a Federal nonworkday (a Saturday, Sunday, legal holiday, or a day which by statute or Executive Order is declared to be a nonworkday for Federal employees), the time is extended to the next succeeding workday.

(d) *Outpatient diabetes self-management training.* CMS makes payment in half-hour increments to an entity for the furnishing of outpatient diabetes self-management training on or after the approval date CMS approves the entity to furnish the services under part 410, subpart H of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 65 FR 83153, Dec. 29, 2000]

Subpart D—To Whom Payment Is Ordinarily Made

§ 424.50 Scope.

(a) This subpart specifies to whom Medicare payment is ordinarily made for different kinds of services.

(b) Subpart E of this part sets forth provisions applicable in special situations.

(c) Subpart F of this part specifies the exceptional circumstances under which payment may be made to an assignee or reassignee.

§ 424.51 Payment to the provider.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, Medicare pays the provider for services furnished by a provider.

(b) *Exception.* Medicare pays the beneficiary for outpatient hospital services if the hospital has collected an amount in excess of the unmet deductible and coinsurance, as specified in § 489.30(b)(4) of this chapter.

§ 424.52 Payment to a nonparticipating hospital.

Medicare pays a nonparticipating hospital for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a U.S. hospital, if the hospital has in effect an election to claim payment in accordance with subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a U.S. hospital, if the hospital meets the requirements of § 424.55 for payment as a supplier.

(c) Emergency or nonemergency inpatient services furnished by a foreign hospital if the hospital has in effect an election to claim payment in accordance with subpart G of this part.

§ 424.53 Payment to the beneficiary.

Medicare pays the beneficiary for the following services, if covered, in the specified circumstances:

(a) Emergency inpatient and outpatient services furnished by a nonparticipating U.S. hospital that has not elected to claim payment in accordance with subpart G of this part.

(b) Certain medical and other health services covered under Medicare Part B and furnished by a nonparticipating U.S. hospital, if the hospital does not receive assigned payment as a supplier under § 424.55.

(c) Emergency or nonemergency services furnished by a foreign hospital if the hospital does not have in effect an election to claim payment in accordance with subpart H of this part.

(d) Physician and ambulance services furnished outside the United States.

(e) Services furnished by a supplier if the claim has not been assigned to the supplier.

§ 424.54 Payment to the beneficiary's legal guardian or representative payee.

Medicare may pay amounts due a beneficiary to the beneficiary's legal guardian or representative payee.

§ 424.55 Payment to the supplier.

(a) Medicare pays the supplier for covered services if the beneficiary (or the person authorized to request payment on the beneficiary's behalf) assigns the claim to the supplier and the supplier accepts assignment.

(b) In accepting assignment, the supplier agrees to the following:

(1) To accept, as full charge for the service, the amount approved by the carrier as the basis for determining the Medicare Part B payment (the reasonable charge or the lesser of the fee schedule amount and the actual charge).

(2) To limit charges to the beneficiary or any other source as follows:

(i) To collect nothing for those services for which Medicare pays 100 percent of the Medicare approved amount.

(ii) To collect only the difference between the Medicare approved amount and the Medicare Part B payment (for example, the amount of any reduction in incurred expenses under § 410.155(c), any applicable deductible amount, and any applicable coinsurance amount) for services for which Medicare pays less than 100 percent of the approved amount.

(3) Not to charge the beneficiary when Medicare paid for services determined to be ''not reasonable or necessary'' if—

(i) The beneficiary was without fault in the overpayment; and

(ii) The determination that the payment was incorrect was made by the carrier after the third year following the year in which the carrier sent notice to the beneficiary that it approved the payment.

(c) *Exception*. In situations when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

[53 FR 6634, Mar. 2, 1988, as amended at 63 FR 20130, Apr. 23, 1998; 69 FR 66426, Nov. 15, 2004]

§ 424.56 Payment to a beneficiary and to a supplier.

(a) *Conditions for split payment*. If the beneficiary assigns the claim after paying part of the bill, payment may be made partly to the beneficiary and partly to the supplier.

(b) *Payment to the supplier*. Payment to the supplier who submits the assigned claim is for whichever of the following amounts is less:

(1) The reasonable charge minus the amount the beneficiary had already paid to the supplier; or

(2) The full Part B benefit due for the services furnished.

(c) *Payment to the beneficiary.* Any part of the Part B benefit which, on the basis of paragraph (b) of this section, is not payable to the supplier, is paid to the beneficiary.

(d) *Examples.*

Example 1. An assigned bill of $300 on which partial payment of $100 has been made is submitted to the carrier. The carrier determines that $300 is the reasonable charge for the service furnished. Total payment due is 80 percent of $300 or $240. Of this amount, $200 (the difference between the $100 partial payment and the $300 reasonable charge) is paid to the supplier. The remaining $40 is paid to the beneficiary.

Example 2. An assigned bill of $325 on which partial payment of $275 has been made is submitted to the carrier. The carrier determines that $275 is the reasonable charge for the services. Total payment due is 80 percent of $275 or $220. The $220 is paid to the beneficiary, since any payment to the supplier, when added to the $275 partial payment would exceed the reasonable charge for the services furnished.

[53 FR 6641, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

(a) *Definitions.* As used in this section, the following definitions apply:

DMEPOS stands for durable medical equipment, prosthetics, orthotics and supplies.

DMEPOS supplier means an entity or individual, including a physician or a Part A provider, which sells or rents Part B covered items to Medicare beneficiaries and which meets the standards in paragraph (c) of this section.

Medicare covered items means medical equipment and supplies as defined in section 1834(j)(5) of the Act.

(b) *General rule.* A DMEPOS supplier must meet the following conditions in order to be eligible to receive payment for a Medicare-covered item:

(1) The supplier has submitted a completed application to CMS to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations it uses to furnish Medicare-covered DMEPOS, with the exception of locations that it uses solely as warehouses or repair facilities.)

(2) The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges. (CMS issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service.

(3) CMS has not revoked or excluded the DMEPOS supplier's privileges during the period which the item was furnished has not been revoked or excluded.

(4) A supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician's license.)

(5) The supplier has furnished to CMS all information or documentation required to process the claim.

(c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards. The supplier:

(1) Operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements;

(2) Has not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change.);

(3) Must have the application for billing privileges signed by an individual whose signature binds a supplier;

(4) Fills orders, frabicates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. If it does, it must provide, upon request, copies of contracts or

other documentation showing compliance with this standard. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal Government Executive Branch procurement or nonprocurement program or activity;

(5) Advises beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental durable medical equipment, as defined in § 414.220(a) of this subchapter. (The supplier must provide, upon request, documentation that it has provided beneficiaries with this information, in the form of copies of letters, logs, or signed notices.);

(6) Honors all warranties expressed and implied under applicable State law. A supplier must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or for services covered under warranty. This standard applies to all purchased and rented items, including capped rental items, as described in § 414.229 of this subchapter. The supplier must provide, upon request, documentation that it has provided beneficiaries with information about Medicare covered items covered under warranty, in the form of copies of letters, logs, or signed notices;

(7) Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location;

(8) Permits CMS, or its agents to conduct on-site inspections to ascertain supplier compliance with the requirements of this section. The supplier location must be accessible during reasonable business hours to beneficiaries and to CMS, and must maintain a visible sign and posted hours of operation;

(9) Maintains a primary business telephone listed under the name of the business locally or toll-free for beneficiaries. The supplier must furnish information to beneficiaries at the time of delivery of items on how the beneficiary can contact the supplier by telephone. The exclusive use of a beeper number, answering service, pager, facsimile machine, car phone, or an answering machine may not be used as the primary business telephone for purposes of this regulation;

(10) Has a comprehensive liability insurance policy in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed;

(11) Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:

(i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(12) Must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively);

(13) Must answer questions and respond to complaints a beneficiary has about the Medicare-covered item that was sold or rented. A supplier must

refer beneficiaries with Medicare questions to the appropriate carrier. A supplier must maintain documentation of contacts with beneficiaries regarding complaints or questions;

(14) Must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries. The item must function as required and intended after being repaired or replaced;

(15) Must accept returns from beneficiaries of substandard (less than full quality for the particular item or unsuitable items, inappropriate for the beneficiary at the time it was fitted and rented or sold);

(16) Must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item;

(17) Must comply with the disclosure provisions in § 420.206 of this subchapter;

(18) Must not convey or reassign a supplier number;

(19) Must have a complaint resolution protocol to address beneficiary complaints that relate to supplier standards in paragraph (c) of this section and keep written complaints, related correspondence and any notes of actions taken in response to written and oral complaints. Failure to maintain such information may be considered evidence that supplier standards have not been met. (This information must be kept at its physical facility and made available to CMS, upon request.);

(20) Must maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) A summary of the complaint; the date it was received; the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(21) Provides to CMS, upon request, any information required by the Medicare statute and implementing regulations.

(d) *Failure to meet standards.* CMS will revoke a supplier's billing privileges if it is found not to meet the standards in paragraphs (b) and (c) of this section. (The revocation is effective 15 days after the entity is sent notice of the revocation, as specified in § 405.874 of this subchapter.)

(e) *Renewal of billing privileges.* A supplier must renew its application for billing privileges every 3 years after the billing privileges are first granted. (Each supplier must complete a new application for billing privileges 3 years after its last renewal of privileges.)

[65 FR 60377, Oct. 11, 2000]

Subpart E—To Whom Payment is Made in Special Situations

§ 424.60 Scope.

(a) This subpart sets forth provisions applicable to payment after the beneficiary's death and payment to entities that provide coverage complementary to Medicare Part B.

(b) The provisions applicable to payment for services excluded as custodial care or services not reasonable and necessary are set forth in §§ 405.332 through 405.336 of this chapter.

[53 FR 6634, Mar. 2, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.62 Payment after beneficiary's death: Bill has been paid.

(a) *Scope.* This section specifies the persons whom Medicare pays, and the conditions for payments, when the beneficiary has died and the bill has been paid.

(b) *Situation.* (1) The beneficiary has received covered services for which he could receive direct payment under § 424.53.

(2) The beneficiary died without receiving Medicare payment.

(3) The bill has been paid.

(c) *Persons whom Medicare pays.* In the situation described in paragraph (b) of this section, Medicare pays the following persons in the specified circumstances:

(1) The person or persons who, without a legal obligation to do so, paid for the services with their own funds, before or after the beneficiary's death.

(2) The legal representative of the beneficiary's estate if the services were paid for by the beneficiary before he or she died, or with funds from the estate.

(3) If the deceased beneficiary or his or her estate paid for the services and no legal representative of the estate has been appointed, the survivors, in the following order of priority:

(i) The person found by SSA to be the surviving spouse, if he or she was either living in the same household with the deceased at the time of death, or was, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(ii) The child or children, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(iii) The parent or parents, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent);

(iv) The person found by SSA to be the surviving spouse who was not living in the same household with the deceased at the time of death and was not, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(v) The child or children who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(vi) The parent or parents who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent).

(4) If none of the listed relatives survive, no payment is made.

(5) If the services were paid for by a person other than the deceased beneficiary, and that person died before payment was completed, Medicare does not pay that person's estate. Medicare pays a surviving relative of the deceased beneficiary in accordance with the priorities in paragraph (c)(3) of this section. If none of those relatives survive. Medicare pays the legal representative of the deceased beneficiary's estate. If there is no legal representative of the estate, no payment is made.

(d) *Amount of payment.* The amount of payment is the amount due, including unnegotiated checks issued for the purpose of making direct payment to the beneficiary.

(e) *Conditions for payment.* For payment to be made under this section—

(1) The person who claims payment must meet the following requirements:

(i) Submit a claim on a CMS-prescribed form and an itemized bill in accordance with the requirements of this subpart. (See paragraph (g) of this section for an exception.)

(ii) Provide evidence that the services were furnished if the intermediary or carrier requests it.

(iii) Provide evidence of payment of the bill and of the identity of the person who paid it.

(2) If a person claims payment as the legal representative of the deceased beneficiary's estate, he or she must also submit a copy of the papers showing appointment as legal representative.

(3) If a person claims payment as a survivor of the beneficiary, he or she must also submit evidence, if the intermediary or carrier requests it, that he or she is highest on the priority list of paragraph (c)(3) of this section.

(f) *Evidence of payment.* Evidence of payment may be—

(1) A receipted bill, or a properly completed ''Report of Services'' section of a claim form, showing who paid the bill;

(2) A cancelled check;

(3) A written statement from the provider or supplier or an authorized staff member; or

(4) Other probative evidence.

(g) *Exception: Claim submitted before beneficiary died.* If a claim and itemized bill has been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form and

itemized bill is not required; any written request by the person seeking payment is sufficient.

§ 424.64 Payment after beneficiary's death: Bill has not been paid.

(a) *Scope*. This section specifies whom Medicare pays, and the conditions for payment when the beneficiary has died and the bill has not been paid.

(b) *Situation*. (1) The beneficiary has received covered Part B services furnished by a physician or other supplier.

(2) The beneficiary died without making an assignment to the physician or other supplier or receiving Medicare payment.

(3) The bill has not been paid.

(c) *To whom payment is made*. In the situation described in paragraph (b) of this section, Medicare pays as follows:

(1) *Payment to the supplier*. Medicare pays the physician or other supplier if he or she—

(i) Files a claim on a CMS-prescribed form in accordance with the applicable requirements of this subpart;

(ii) Upon request from the carrier, provides evidence that the services for which it claims payment were, in fact, furnished; and

(iii) Agrees in writing to accept the reasonable charge as the full charge for the services.

(2) *Payment to a person who assumes legal obligation to pay for the services*. If the physician or other supplier does not agree to accept the reasonable charge as full charge for the service, Medicare pays any person who submits to the carrier all of the following:

(i) A statement indicating that he or she has assumed legal obligation to pay for the services.

(ii) A claim on a CMS-prescribed form in accordance with the requirements of this subpart. (If a claim had been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form is not required; a written request by the person seeking payment meets the requirement for a claim.)

(iii) An itemized bill that identifies the claimant as the person to whom the physician or other supplier holds responsible for payment. (If such an itemized bill had been submitted by or on behalf of the beneficiary before he or she died, submission of another itemized bill is not required.)

(iv) If the intermediary or carrier requests it, evidence that the services were actually furnished.

[53 FR 6634, Mar. 2, 1988, as amended at 53 FR 28388, July 28, 1988]

§ 424.66 Payment to entities that provide coverage complementary to Medicare Part B.

(a) *Conditions for payment*. Medicare may pay an entity for Part B services furnished by a physician or other supplier if the entity meets all of the following requirements:

(1) Provides coverage of the service under a complementary health benefit plan (this is, the coverage that the plan provides is complementary to Medicare benefits and covers only the amount by which the Part B payment falls short of the approved charge for the service under the plan).

(2) Has paid the person who provided the service an amount (including the amount payable under the Medicare program) that the person accepts as full payment.

(3) Has the written authorization of the beneficiary (or of a person authorized to sign claims on his behalf under § 424.36) to receive the Part B payment for the services for which the entity pays.

(4) Relieves the beneficiary of liability for payment for the service and will not seek any reimbursement from the beneficiary, his or her survivors or estate.

(5) Submits any information CMS or the carrier may request, including an itemized physician or supplier bill, in order to apply the requirements under the Medicare program.

(6) Identifies and excludes from its requests for payment all services for which Medicare is the secondary payer.

(b) *Services paid for by the entity*. An entity is not required to pay and claim reimbursement for all Part B services furnished to members of its plans. However, if it does not pay and claim reimbursement for all those services, it must establish in advance precise criteria for identifying the services for

which it will pay and claim reimbursement.

[53 FR 28388, July 28, 1988; 53 FR 40231, Oct. 14, 1988]

Subpart F—Limitations on Assignment and Reassignment of Claims

§ 424.70 Basis and scope.

(a) *Statutory basis*. This subpart implements sections 1815(c) and 1842(b)(6) of the Act, which establish limitations on who may receive payments due a provider or supplier of services or a beneficiary.

(b) *Scope*. This subpart—

(1) Prohibits the assignment, reassignment, or other transfer of the right to Medicare payments except under specified conditions;

(2) Sets forth the sanctions that CMS may impose on a provider or supplier that violates this prohibition, or on a supplier that violates the conditions to which it agreed in accepting assignment from the individual; and

(3) Specifies the conditions for payment under court-ordered assignments or reassignments.

§ 424.71 Definitions.

As used in this subpart, unless the context indicates otherwise—

Court of competent jurisdiction means a court that has jurisdiction over the subject matter and the parties before it.

Facility means a hospital or other institution that furnishes health care services to inpatients.

Entity means a person, group, or facility that is enrolled in the Medicare program.

Power of attorney means any written documents by which a principal authorizes an agent to—

(1) Receive, in the agent's name, any payments due the principal;

(2) Negotiate checks payable to the principal; or

(3) Receive, in any other manner, direct payment of amounts due the principal.

[53 FR 6634, Mar. 2, 1988, as amended at 69 FR 66426, Nov. 15, 2004]

§ 424.73 Prohibition of assignment of claims by providers.

(a) *Basic prohibition*. Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a provider to any other person under assignment, or power of attorney, or any other direct payment arrangement.

(b) *Exceptions to the prohibition*—(1) *Payment to a government agency or entity*. Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under an assignment by the provider.

(2) *Payment under assignment established by court order*. Medicare may pay under an assignment established by, or in accordance with, the order of a court of competent jurisdiction if the assignment meets the conditions set forth in § 424.90.

(3) *Payment to an agent*. Medicare may pay an agent who furnishes billing and collection services to the provider if the following conditions are met:

(i) The agent receives the payment under an agency agreement with the provider;

(ii) The agent's compensation is not related in any way to the dollar amounts billed or collected;

(iii) The agent's compensation is not dependent upon the actual collection of payment;

(iv) The agent acts under payment disposition instructions that the provider may modify or revoke at any time; and

(v) The agent, in receiving the payment, acts only on behalf of the provider.

Payment to an agent will always be made in the name of the provider.

§ 424.74 Termination of provider agreement.

CMS may terminate a provider agreement, in accordance with § 489.53(a)(1) of this chapter, if the provider—

(a) Executes or continues a power of attorney, or enters into or continues any other arrangement, that authorizes or permits payment contrary to the provisions of this subpart; or

(b) Fails to furnish, upon request by CMS or the intermediary, evidence

necessary to establish compliance with the requirements of this subpart.

§ 424.80 Prohibition of reassignment of claims by suppliers.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a supplier under an assignment to any other person under reassignment, power of attorney, or any other direct arrangement. Nothing in this section alters a party's obligations under the anti-kickback statute (section 1128B(b) of the Act), the physician self-referral prohibition (section 1877 of the Act), the rules regarding physician billing for purchased diagnostic tests (§ 414.50 of this chapter), the rules regarding payment for services and supplies incident to a physician's professional services (§ 410.26 of this chapter), or any other applicable Medicare laws, rules, or regulations.

(b) *Exceptions to the basic rule*—(1) *Payment to employer.* Medicare may pay the supplier's employer if the supplier is required, as a condition of employment, to turn over to the employer the fees for his or her services.

(2) *Payment to an entity under a contractual arrangement.* Medicare may pay an entity enrolled in the Medicare program if there is a contractual arrangement between the entity and the supplier under which the entity bills for the supplier's services, subject to the provisions of paragraph (d) of this section.

(3) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under a reassignment by the supplier.

(4) *Payment under a reassignment established by court order.* Medicare may pay under a reassignment established by, or in accordance with, the order of a court competent jurisdiction, if the reassignment meets the conditions set forth in § 424.90.

(5) *Payment to an agent.* Medicare may pay an agent who furnishes billing and collection services to the supplier, or to the employer, facility, or system specified in paragraphs (b) (1), (2) and (3) of this section, if the conditions of § 424.73(b)(3) for payment to a provider's agent are met by the agent of the supplier or of the employer, facility, or system. Payment to an agent will always be made in the name of the supplier or the employer, facility, or system.

(c) *Rules applicable to an employer or entity.* An employer or entity that may receive payment under paragraph (b)(1) or (b)(2) of this section is considered the supplier of those services for purposes of subparts C, D, and E of this part, subject to the provisions of paragraph (d) of this section.

(d) *Reassignment to an entity under a contractual arrangement: Conditions and limitations.* (1) *Liability of the parties.* An entity enrolled in the Medicare program that receives payment under a contractual arrangement under paragraph (b)(2) of this section and the supplier that otherwise receives payment are jointly and severally responsible for any Medicare overpayment to that entity.

(2) *Access to records.* The supplier furnishing the service has unrestricted access to claims submitted by an entity for services provided by that supplier.

[53 FR 6634, Mar. 2, 1988, as amended at 54 FR 4027, Jan. 27, 1989; 69 FR 66426, Nov. 15, 2004; 70 FR 16722, Apr. 1, 2005]

§ 424.82 Revocation of right to receive assigned benefits.

(a) *Scope.* This section sets forth the conditions and procedures for revocation of the right of a supplier or other party to receive Medicare payments.

(b) *Definition.* As used in this section, *other party* means an employer, facility, or health care delivery system to which Medicare may make payment under § 424.80(b) (1), (2), or (3).

(c) *Basis for revocation.* CMS may revoke the right of a supplier or other party to receive Medicare payments if the supplier or other party, after warning by CMS or the carrier—

(1) Violates the terms of assignment in § 424.55(b).

(2) Continues collection efforts or fails to refund moneys incorrectly collected, in violation of the terms of assignment in § 424.55(b).

(3) Executes or continues in effect a reassignment or power of attorney or any other arrangement that seeks to

obtain payment contrary to the provisions of § 424.80; or

(4) Fails to furnish evidence necessary to establish its compliance with the requirements of § 424.80.

(d) *Proposed revocation: Notice and opportunity for review.* If CMS proposes to revoke the right to payment in accordance with paragraph (c) of this section, it will send the supplier or other party a written notice that—

(1) States the reasons for the proposed revocation; and

(2) Provides an opportunity for the supplier or other party to submit written argument and evidence against the proposed revocation. CMS usually allows 15 days from the date on the notice, but may extend or reduce the time as circumstances require.

(e) *Actual revocation: Timing, notice, and opportunity for hearing*—(1) *Timing.* CMS determines whether to revoke after considering any written argument or evidence submitted by the supplier or other party or, if none is submitted, at the expiration of the period specified in the notice of proposed revocation.

(2) *Notice and opportunity for hearing.* The notice of revocation specifies—

(i) The reasons for the revocation;

(ii) That the revocation is effective as of the date on the notice;

(iii) That the supplier or other party may, within 60 days from the date on the notice (or a longer period if the notice so specifies), request an administrative hearing and may be represented by counsel or other qualified representative.

(iv) That the carrier will withhold payment on any claims submitted by the supplier or other party until the period for requesting a hearing expires or, if a hearing is requested, until the hearing officer issues a decision;

(v) That if the hearing decision reverses the revocation, the carrier will pay the supplier's or other party's claims; and

(vi) That if a hearing is not requested or the hearing decision upholds the revocation, payment will be made to the beneficiary or to another person or agency authorized to receive payment on his or her behalf.

[53 FR 6644, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.83 Hearings on revocation of right to receive assigned benefits.

If the supplier or other party requests a hearing under § 424.82(e)(2)—

(a) The hearing is conducted—

(1) By a CMS hearing official who was not involved in the decision to revoke; and

(2) In accordance with the procedures set forth in §§ 405.824 through 405.833 (but excepting § 405.832(d)) and 405.860 through 405.872 of this chapter. In applying those procedures, ''CMS'' is substituted for ''carrier''; and ''hearing official'', for ''hearing officer''.

(b) As soon as practicable after the close of the hearing, the official who conducted it issues a hearing decision that—

(1) Is based on all the evidence presented at the hearing and included in the hearing record; and

(2) Contains findings of fact and a statement of reasons.

§ 424.84 Final determination on revocation of right to receive assigned benefits.

(a) *Basis of final determination*—(1) *Final determination without a hearing.* If the supplier or other party does not request a hearing, CMS's revocation determination becomes final at the end of the period specified in the notice of revocation.

(2) *Final determination following a hearing.* If there is a hearing, the hearing decision constitutes CMS's final determination.

(b) *Notice of final determination.* CMS sends the supplier or other party a written notice of the final determination and, if there was a hearing, includes a copy of the hearing decision.

(c) *Application of the final determination*—(1) A final determination not to revoke is the final administrative decision by CMS on the matter.

(2) A final determination to revoke remains in effect until CMS finds that the reason for the revocation has been removed and that there is reasonable assurance that it will not recur.

(d) *Effect of revocation when supplier or other party has a financial interest in another entity.* Revocation of the party's right to accept assignment also applies to any corporation, partnership,

or other entity in which the party, directly or indirectly, has or acquires all or all but a nominal part of the financial interest.

[53 FR 6644, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 424.86 Prohibition of assignment of claims by beneficiaries.

(a) *Basic prohibition.* Except as specified in paragraph (b) of this section, Medicare does not pay amounts that are due a beneficiary under § 424.53 to any other person under assignment, power of attorney, or any other direct payment arrangement.

(b) *Exceptions*—(1) *Payment to a government agency or entity.* Subject to the requirements of the Assignment of Claims Act (31 U.S.C. 3727), Medicare may pay a government agency or entity under an assignment by a beneficiary (or by the beneficiary's legal guardian or representative payee).

(2) *Payment under an assignment established by court order.* Medicare may pay under an assignment established by, or in accordance with, a court order if the assignment meets the conditions set forth in § 424.90.

§ 424.90 Court ordered assignments: Conditions and limitations.

(a) *Conditions for acceptance.* An assignment or reassignment established by or in accordance with a court order is effective for Medicare payments only if—

(1) Someone files a certified copy of the court order and of the executed assignment or reassignment (if it was necessary to execute one) with the intermediary or carrier responsible for processing the claim; and

(2) The assignment or reassignment—

(i) Applies to all Medicare benefits payable to a particular person or entity during a specified or indefinite time period; or

(ii) Specifies a particular amount of money, payable to a particular person or entity by a particular intermediary or carrier.

(b) *Retention of authority to reduce interim payments to providers.* A court-ordered assignment does not preclude the intermediary or carrier from reducing interim payments, as set forth in § 413.64(i) of this chapter, if the provider or assignee is in imminent danger of insolvency or bankruptcy.

(c) *Liability of the parties.* The party that receives payments under a court-ordered assignment or reassignment that meets the conditions of paragraph (a) of this section and the party that would have received payment if the court order had not been issued are jointly and severally responsible for any Medicare overpayment to the former.

Subpart G—Special Conditions: Emergency Services Furnished by a Nonparticipating Hospital

§ 424.100 Scope.

This subpart sets forth procedures and criteria that are followed in determining whether Medicare will pay for emergency services furnished by a hospital that is located in the United States and does not have in effect a provider agreement, that is, an agreement to participate in Medicare.

§ 424.101 Definitions.

As used in this subpart, unless the context indicates otherwise—

Emergency services means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.

Hospital means a facility that—

(1) Is primarily engaged in providing, by or under the supervision of doctors of medicine or osteopathy, inpatient services for the diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled;

(2) Is not primarily engaged in providing skilled nursing care and related services for patients who require medical or nursing care, as described in section 1861(j)(1)(A) of the Act;

(3) Provides 24-hour nursing service in accordance with section 1861(e)(5) of the Act; and

(4) Is licensed, or is approved as meeting the standards for licensing, by the State or local licensing agency.

Reasonable charges means customary charges insofar as they are reasonable.

§ 424.102 Situations that do not constitute an emergency.

Without additional evidence of a threat to life or health, the following situations do not in themselves indicate a need for emergency services:

(a) Lack of care at home.

(b) Lack of transportation to a participating hospital.

(c) Death of the patient in the hospital.

§ 424.103 Conditions for payment for emergency services.

Medicare pays for emergency services furnished to a beneficiary by a nonparticipating hospital or under arrangements made by such a hospital if the conditions of this section are met.

(a) *General requirements.* (1) The services are of the type that Medicare would pay for if they were furnished by a participating hospital.

(2) The hospital has in effect an election to claim payment for all emergency services furnished in a calendar year in accordance with § 424.104.

(3) The need for emergency services arose while the beneficiary was not an inpatient in a hospital.

(4) In the case of inpatient hospital services, the services are furnished during a period in which the beneficiary could not be safely discharged or transferred to a participating hospital or other institution.

(5) The determination that the hospital was the most accessible hospital available and equipped to furnish the services is made in accordance with § 424.106.

(b) *Medical information requirements.* A physician (or, if appropriate, the hospital) submits medical information that—

(1) Describes the nature of the emergency and specifies why it required that the beneficiary be treated in the most accessible hospital;

(2) Establishes that all the conditions in paragraph (a) of this section are met; and

(3) Indicates when the emergency ended, which, for inpatient hospital services, is the earliest date on which the beneficiary could be safely discharged or transferred to a participating hospital or other institution.

§ 424.104 Election to claim payment for emergency services furnished during a calendar year.

(a) *Terms of the election.* The hospital agrees to the following:

(1) To comply with the provisions of subpart C of part 489 of this chapter relating to charges for items and services the hospital may make to the beneficiary, or any other person on his or her behalf.

(2) To comply with the provisions of subpart D of part 489 of this chapter relating to proper disposition of monies incorrectly collected from, or on behalf of a beneficiary.

(3) To request payment under the Medicare program based on amounts specified in § 413.74 of this chapter.

(b) *Filing of election statement.* An election statement must be filed on a form designated by CMS, signed by an authorized official of the hospital, and either received by CMS, or postmarked, before the close of the calendar year of election.

(c) *Acceptance and effective date of election.* If CMS accepts the election statement, the election is effective as of the earliest day of the calendar year of election from which CMS determines the hospital has been in continuous compliance with the requirements of section 1814(d) of the Act.

(d) *Appeal by hospital.* Any hospital dissatisfied with a determination that it does not qualify to claim reimbursement shall be entitled to appeal the determination as provided in part 498 of this chapter.

(e) *Conditions for reinstatement after notice of failure to continue to qualify.* If CMS has notified a hospital that it no longer qualifies to receive reimbursement for a calendar year, CMS will not accept another election statement from that hospital until CMS finds that—

(1) The reason for its failure to qualify has been removed; and

(2) There is reasonable assurance that it will not recur.

§ 424.106 Criteria for determining whether the hospital was the most accessible.

(a) *Basic requirement.* (1) The hospital must be the most accessible one available and equipped to furnish the services.

(2) CMS determines accessibility based on the factors specified in paragraphs (b) and (c) of this section and the conditions set forth in paragraph (d) of this section.

(b) *Factors that are considered.* CMS considers the following factors in determining whether a nonparticipating hospital in a rural area meets the accessibility requirements:

(1) The relative distances of participating and nonparticipating hospitals in the area.

(2) The transportation facilities available to these hospitals.

(3) The quality of the roads to each hospital.

(4) The availability of beds at each hospital.

(5) Any other factors that bear on whether or not the services could be provided sooner in the nonparticipating hospitals than in a participating hospital in the general area.

In urban and suburban areas where both participating and nonparticipating hospitals are similarly available, CMS presumes that the services could have been provided in a participating hospital unless clear and convincing evidence shows that there was a medical or practical need to use the nonparticipating hospital.

(c) *Factors that are not considered.* CMS gives no consideration to the following factors in determining whether the nonparticipating hospital was the most accessible hospital:

(1) The personal preference of the beneficiary, the physician, or members of the family.

(2) The fact that the attending physician did not have staff privileges in a participating hospital which was available and the most accessible to the beneficiary.

(3) The location of previous medical records.

(d) *Conditions under which the accessibility requirement is met.* If a beneficiary must be taken to a hospital immediately for required diagnosis and treatment, the nonparticipating hospital meets the accessibility requirement if—

(1) It was the nearest hospital to the point where the emergency occurred, it was medically equipped to handle the type of emergency, and it was the most accessible, on the basis of the factors specified in paragraph (b) of this section; or

(2) There was a closer participating hospital equipped to handle the emergency, but the participating hospital did not have a bed available or would not accept the individual.

§ 424.108 Payment to a hospital.

(a) *Conditions for payment.* Medicare pays the hospital for emergency services if the hospital—

(1) Has in effect a statement of election to claim payment for all covered emergency services furnished during a calendar year, in accordance with § 424.104;

(2) Claims payment in accordance with § 424.32; and

(3) Submits evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Subsequent claims.* If the hospital files subsequent claims because the initial claim did not include all the services furnished, those claims must include physicians' statements that—

(1) Contain sufficient information to clearly establish that, when the additional services were furnished, the emergency still existed; and

(2) Indicate when the emergency ended, which, for inpatient hospital services, is the earliest date on which the beneficiary could be safely discharged or transferred to a participating hospital or other institution.

§ 424.109 Payment to the beneficiary.

Medicare pays the beneficiary for emergency services if the following conditions are met:

(a) The hospital does not have in effect an election to claim payment.

(b) The beneficiary, or someone on his or her behalf, submits—

(1) A claim that meets the requirements of § 424.32;

(2) An itemized hospital bill; and

(3) Evidence requested by CMS to establish that the services meet the requirements of this subpart.

Subpart H—Special Conditions: Services Furnished in a Foreign Country

§ 424.120 Scope.

This subpart sets forth the conditions for payment for services furnished in a foreign country.

§ 424.121 Scope of payments.

Subject to the conditions set forth in this subpart—

(a) Medicare Part A pays, in the amounts specified in § 413.74 of this chapter, for emergency and nonemergency inpatient hospital services furnished by a foreign hospital.

(b) Medicare Part B pays for certain physicians' services and ambulance services furnished in connection with covered inpatient care in a foreign hospital, as specified in § 424.124.

(c) All other services furnished outside the United States are excluded from Medicare coverage, as specified in § 405.313 of this chapter.

§ 424.122 Conditions for payment for emergency inpatient hospital services.

Medicare Part A pays for emergency inpatient hospital services furnished by a foreign hospital if the following conditions are met:

(a) At the time of the emergency that required the inpatient hospital services, the beneficiary was—

(1) In the United States; or

(2) In Canada traveling between Alaska and another State without unreasonable delay and by the most direct route.

(b) The foreign hospital was closer to, or more accessible from, the site of the emergency than the nearest United States hospital equipped to deal with, and available to treat, the individual's illness or injury.

(c) The conditions for payment for emergency services set forth in § 424.103 are met.

(d) The hospital is a hospital as defined in § 424.101, and is licensed, or approved as meeting the conditions for licensing, by the appropriate agency of the country in which it is located.

(e) The determination of whether the hospital was more accessible is made in accordance with § 424.106.

§ 424.123 Conditions for payment for nonemergency inpatient services furnished by a hospital closer to the individual's residence.

Medicare Part A pays for inpatient hospital services furnished by a foreign hospital if the following conditions are met:

(a) The beneficiary is a resident of the United States.

(b) The foreign hospital is closer or more accessible to the beneficiary's residence than the nearest United States hospital equipped to deal with, and available to treat, the individual's illness or injury.

(c) The foreign hospital is—

(1) A hospital as defined in § 424.101 and, it is licensed, or approved as meeting the conditions for licensing, by the appropriate agency of the country in which it is located; and

(2) Accredited by the Joint Commission on Accreditation of Hospitals (JCAH) or accredited or approved by a program of the country where it is located under standards that CMS finds to be essentially equivalent to those of the JCAH.

(d) The services are covered services that Medicare would pay for if they were furnished by a participating hospital.

§ 424.124 Conditions for payment for physician services and ambulance services.

(a) *Basic rules.* Medicare Part B pays for physician and ambulance services if—

(1) They are furnished—

(i) To an individual who is entitled to Part B benefits; and

(ii) In connection with covered inpatient hospital services; and

(2) They meet the conditions set forth in paragraphs (b) and (c) of this section.

(b) *Physician services.* (1) The physician services are services covered under Medicare Part B and are furnished—

(i) In the hospital, during a period of covered inpatient services; or

(ii) Outside the hospital, on the day of admission and for the same condition that required inpatient admission; and

(2) The physician is legally authorized to practice in the country where he or she furnishes the services.

(c) *Ambulance services.* The ambulance services are—

(1) Necessary because the use of other means of transportation is contraindicated by the beneficiary's condition; and

(2) Furnished by an ambulance that meets the definition in § 410.41 of this chapter.

[53 FR 6646, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 64 FR 3649, Jan. 25, 1999]

§ 424.126 Payment to the hospital.

(a) *Conditions for payment.* Medicare pays the hospital if it—

(1) Has in effect an election that—

(i) Meets the requirements set forth in § 424.104; and

(ii) Reflects the hospital's intent to claim for all covered services furnished during a calendar year.

(2) Claims payment in accordance with §§ 424.32 and 413.74 of this chapter; and

(3) Submits evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Amount of payment.* Payment is made (in accordance with § 413.74 of this chapter) on the basis of 100 percent of the hospital's customary charges, subject to the applicable deductible and coinsurance provisions set forth elsewhere in this chapter.

§ 424.127 Payment to the beneficiary.

(a) *Conditions for payment of inpatient hospital services.* Medicare pays the beneficiary if—

(1) The hospital does not have in effect an election to claim payment; and

(2) The beneficiary, or someone on his or her behalf, submits—

(i) A claim in accordance with § 424.32;

(ii) An itemized hospital bill; and

(iii) Evidence requested by CMS to establish that the services meet the requirements of this subpart.

(b) *Amount payable for inpatient hospital services.* The amount payable to the beneficiary is determined in accordance with § 424.109(b).

(c) *Conditions for payment for Part B services.* Medicare pays the beneficiary for physicians' services and ambulance services as specified in § 424.121, if an itemized bill for the services is submitted by the beneficiary or someone on his or her behalf and the conditions of § 424.126(a) (2) and (3) are met.

(d) The amount payable to the beneficiary is determined in accordance with § 410.152 of this chapter.

Subparts I–L [Reserved]

Subpart M—Replacement and Reclamation of Medicare Payments

§ 424.350 Replacement of checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.

(a) *U.S. Government checks*—(1) *Responsibility.* The Treasury Department is responsible for the investigation and settlement of claims in connection with Treasury checks issued on behalf of CMS.

(2) *Action by CMS.* CMS forwards reports of lost, stolen, defaced, mutilated, destroyed, or forged Treasury checks to the Treasury Department disbursing center responsible for issuing checks.

(3) *Action by the Treasury Department.* The Treasury Department will replace and begin reclamation of Treasury checks in accordance with Treasury Department regulations (31 CFR parts 235, 240, and 245).

(b) *Intermediary and carrier benefit checks.* Checks issued by intermediaries and carriers are drawn on commercial banks and are not subject to the Federal laws and Treasury Department regulations that govern Treasury checks. Replacement procedures are carried out in accordance with § 424.352 under applicable State law (including any Federal banking laws or regulations that may affect the relevant State proceedings).

[58 FR 65129, Dec. 13, 1993]

§ 424.352 Intermediary and carrier checks that are lost, stolen, defaced, mutilated, destroyed or paid on forged endorsements.

(a) When an intermediary or carrier is notified by a payee that a check has been lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsement, the intermediary or carrier contacts the commercial bank on whose paper the check was drawn and determines whether the check has been negotiated.

(b) If the check has been negotiated—

(1) The intermediary or carrier provides the payee with a copy of the check and other pertinent information (such as a claim form, affidavit or questionnaire to be completed by the payee) required to pursue his or her claim in accordance with State law and commercial banking regulations.

(2) To pursue the claim, the payee must examine the check and certify (by completing the claim form, questionnaire or affidavit) that the endorsement is not the payee's.

(3) The claim form and other pertinent information is sent to the intermediary or carrier for review and processing of the claim.

(4) The intermediary or carrier reviews the payee's claim. If the intermediary or carrier determines that the claim appears to be valid, it forwards the claim and a copy of the check to the issuing bank. The intermediary or carrier takes further action to recover the proceeds of the check in accordance with the State law and regulations.

(5) Once the intermediary or carrier recovers the proceeds of the initial check, the intermediary or carrier issues a replacement check to the payee.

(6) If the bank of first deposit refuses to settle on the check for good cause, the payee must pursue the claim on his or her own and the intermediary or carrier will not reissue the check to the payee.

(c) If the check has not been negotiated—

(1) The intermediary or carrier arranges with the bank to stop payment on the check; and

(2) Except as provided in paragraph (d), the intermediary or carrier reissues the check to the payee.

(d) No check may be reissued under (c)(2) unless the claim for a replacement check is received by the intermediary or carrier no later than 1 year from the date of issuance of the original check, unless State law (including any applicable Federal banking laws or regulations that may affect the relevant State proceeding) provides a longer period which will control.

[58 FR 65130, Dec. 13, 1993]

PART 426—REVIEWS OF LOCAL AND NATIONAL COVERAGE DETERMINATIONS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh)

SOURCE: 68 FR 63716, Nov. 7, 2003, unless otherwise noted.

Subpart A—General Provisions

§ 426.100 Basis and scope.

(a) *Basis*. This part implements sections 1869(f)(1) and (f)(2) of the Act, which provide for the review of LCDs, NCDs, and certain determinations that are deemed to be NCDs by statute.

(b) *Scope*. This subpart establishes the requirements and procedures for the review of LCDs and NCDs.

§ 426.110 Definitions.

For the purposes of this part, the following definitions apply:

Aggrieved party means a Medicare beneficiary, or the estate of a Medicare beneficiary, who—

(1) Is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare+Choice plan, or in another Medicare managed care plan);

(2) Is in need of coverage for a service that is denied based on an applicable LCD (in the relevant jurisdiction) or an NCD, regardless of whether the service was received; and

(3) Has obtained documentation of the need by the beneficiary's treating physician.

Board means the Departmental Appeals Board.

Clinical and scientific experts mean experts that are consulted by the ALJ or Board as independent and impartial individuals, with significant experience and/or published work, pertaining to the subject of the review.

Contractor means a carrier (including a Durable Medical Equipment Regional Carrier), or a fiscal intermediary (including a Regional Home Health Intermediary) that has jurisdiction for the LCD at issue.

Deemed NCD means a determination that the Secretary makes, in response to a request for an NCD under section 1869(f)(4)(B) and (C) of the Act, that no national coverage or noncoverage determination is appropriate, or the Secretary's failure to meet the deadline under section 1869(f)(4)(A)(iv) of the Act.

New evidence means clinical or scientific evidence that was not previously considered by the contractor or CMS before the LCD or NCD was issued.

Party means an aggrieved party, which is an individual, or estate who has a right to participate in the LCD or NCD review process, and, as appropriate, a contractor or CMS.

Proprietary data and *Privileged information* means information from a source external to CMS or a contractor, or protected health information, that meets the following criteria:

(1) It is ordinarily protected from disclosure in accordance with 45 CFR part 164, under the Trade Secrets Act (18 U.S.C. 1905) or under Exemptions 4 or 5 of the Freedom of Information Act (5 U.S.C. 552) as specified in 45 CFR 5.65.

(2) The party who possesses the right to protection of the information from public release or disclosure has not provided its consent to the public release or disclosure of the information. Any information submitted by the public that is not marked proprietary is not considered proprietary.

Reasonableness standard means the standard that an ALJ or the Board must apply when conducting an LCD or an NCD review. In determining whether LCDs or NCDs are valid, the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Board.

Supplemental LCD/NCD record is a record that the contractor/CMS provides to the ALJ/Board and any aggrieved party and consists of all materials received and considered during a reconsideration. Materials that are already in the record before the ALJ/Board (for example, new evidence presented in the taking of evidence or hearing) need not be provided but may be incorporated by reference in the supplement to the LCD/NCD record. The contractor/CMS may provide statements, evidence, or other submissions to the ALJ/Board during the proceedings, as provided elsewhere in these regulations, but these submissions are not considered as supplementing the LCD/NCD record.

Treating physician means the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge.

§ 426.120 Calculation of deadlines.

In counting days, Saturdays, Sundays, and Federal holidays are included. If a due date falls on a Saturday, Sunday, or Federal holiday, the due date is the next Federal working day.

§ 426.130 Party submissions.

Any party submitting material, except for material for which a privilege is asserted, or proprietary data, to the ALJ or the Board after that party's initial challenge must serve the material on all other parties at the same time.

Subpart B [Reserved]

Subpart C—General Provisions for the Review of LCDs and NCDs

§ 426.300 Review of LCDs, NCDs, and deemed NCDs.

(a) Upon the receipt of an acceptable LCD complaint as described in § 426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in § 426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

§ 426.310 LCD and NCD reviews and individual claim appeals.

(a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

§ 426.320 Who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

§ 426. 325 What may be challenged.

(a) Only LCDs or NCDs (including deemed NCDs) that are currently effective may be challenged.

(b) Some items are not reviewable under this part, including the following:

(1) Pre-decisional materials, including—

(i) Draft LCDs;

(ii) Template LCDs or suggested LCDs; and

(iii) Draft NCDs, including national coverage decision memoranda.

(2) Retired LCDs or withdrawn NCDs.

(3) LCD or NCD provisions that are no longer in effect due to revisions or reconsiderations.

(4) Interpretive policies that are not an LCD or NCD.

(5) Contractor decisions that are not based on section 1862(a)(1)(A) of the Act.

(6) Contractor claims processing edits.

(7) Payment amounts or methodologies.

(8) Procedure coding issues, including determinations, methodologies, definitions, or provisions.

(9) Contractor bulletin articles, educational materials, or Web site frequently asked questions.

(10) Any M+C organization or managed care plan policy, rule, or procedure.

(11) An individual claim determination.

(12) Any other policy that is not an LCD or an NCD as set forth in § 400.202 of this chapter.

§ 426.330 Burden of proof.

During an LCD or NCD review, an aggrieved party bears the burden of proof and the burden of persuasion for the issue(s) raised in a complaint. The burden of persuasion is judged by a preponderance of the evidence.

§ 426.340 Procedures for review of new evidence.

(a) The process for review of new evidence is initiated once the ALJ/Board completes the taking of evidence.

(b) If an aggrieved party has submitted new evidence pertaining to the LCD/NCD provision(s) in question, and the ALJ or the Board finds that evidence admissible, the ALJ or the Board reviews the record as a whole and decide whether the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard.

(c) If the ALJ or the Board determines that the new evidence does not

have the potential to significantly affect the ALJ's or the Board's evaluation of the LCD/NCD provision(s) in question under the reasonableness standard, this evidence is included in the review record, and the review goes forward to a decision on the merits.

(d) If the ALJ or the Board determines that the new evidence has the potential to significantly affect the ALJ's or the Board's evaluation of the LCD or NCD provision(s) in question under the reasonableness standard, then the ALJ or the Board—

(1) Stays the proceedings and ensures that the contractor or CMS, whichever is appropriate, has a copy of the new evidence for its examination; and

(2) Allows the contractor/CMS 10 days, generally, to examine the new evidence, and to decide whether the contractor or CMS initiates a reconsideration.

(e) If the contractor or CMS informs the ALJ or the Board by the end of the 10 days that a reconsideration is initiated, and then the ALJ or the Board—

(1) Continues the stay in proceedings; and

(2) Sets a reasonable timeframe, not more than 90 days, by which the contractor or CMS completes the reconsideration.

(f) The ALJ or Board lifts the stay in proceedings and continues the review on the challenged provision(s) of the original LCD or NCD, including the new evidence in the review record, if the contractor or CMS—

(1) Informs the ALJ or Board that a reconsideration is not initiated; or

(2) The 90-day reconsideration timeframe is not met.

(g) If an LCD or NCD is reconsidered and revised within the timeframe allotted by the ALJ or Board, then the revised LCD or NCD and any supplement to the LCD or NCD record is forwarded to the ALJ or the Board and all parties and the review proceeds on the LCD or NCD.

Subpart D—Review of an LCD

§ 426.400 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an LCD.

(a) *The complaint.* An aggrieved party may initiate a review of an LCD by filing a written complaint with the office designated by CMS on the Medicare Web site, *http://www.medicare.gov/coverage/static/appeals.asp.*

(b) *Timeliness of a complaint.* An LCD complaint is not considered timely unless it is filed with the office designated by CMS within—

(1) 6 months of the issuance of a written statement from each aggrieved party's treating practitioner, in the case of aggrieved parties who choose to file an LCD challenge before receiving the service; or

(2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an LCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

(1) *Beneficiary-identifying information:*

(i) Name.

(ii) Mailing address.

(iii) State of residence, if different from mailing address.

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) E-mail address, if applicable.

(2) *If the beneficiary has a representative,* the representative-identifying information must include the following:

(i) Name.

(ii) Mailing address.

(iii) Telephone number.

(iv) E-mail address, if any.

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the LCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *LCD-identifying information:*

(i) Name of the contractor using the LCD.

(ii) Title of LCD being challenged.

(iii) The specific provision (or provisions) of the LCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the

aggrieved party thinks that the provision(s) of the LCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that support the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the LCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an LCD by filing a single written complaint with the ALJ if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same LCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The LCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an LCD—

(i) Before receiving the service, must file with the ALJ a joint complaint within 6 months of the written statement from each aggrieved party's treating physician.

(ii) After receiving the service, must file with the ALJ a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.403 Submitting new evidence once an acceptable complaint is filed.

Once an acceptable complaint is filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the ALJ closes the record.

§ 426.405 Authority of the ALJ.

(a) An ALJ conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) An ALJ defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The ALJ has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.400.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on his or her own motion concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceedings in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in § 426.340.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an LCD review for failure to comply with an ALJ order or procedural request without good cause shown.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The ALJ does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings on his or her own motion or on the motion of a non-aggrieved party.

(2) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(3) Review any decisions by contractors to develop a new or revised LCD.

(4) Conduct a review of any draft, retired, archived, template, or suggested LCDs.

(5) Conduct a review of any policy that is not an LCD, as defined in § 400.202 of this chapter.

(6) Conduct a review of any NCD according to section 1869(f)(1)(A)(i) of the Act.

(7) Conduct a review of the merits of an unacceptable LCD complaint as discussed in § 426.410.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his/her representative;

(ii) CMS and/or the contractor; and

(iii) Experts called by the parties or the ALJ.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel the contractor to conduct studies, surveys, or develop new information to support an LCD record.

(12) Deny a contractor the right to reconsider, revise or retire an LCD.

(13) Find invalid applicable Federal statutes, regulations, rulings, or NCDs.

(14) Enter a decision specifying terms to be included in an LCD.

§ 426.406 *Ex parte* contacts.

No party or person (except employees of the ALJ's office) communicates in any way with the ALJ on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 426.410 Docketing and evaluating the acceptability of LCD complaints.

(a) *Docketing the complaint.* The office designated by CMS does the following upon receiving a complaint regarding an LCD:

(1) Dockets the complaint.

(2) Determines whether the complaint is—

(i) The first challenge to a particular LCD; or

(ii) Related to a pending LCD review.

(3) Forwards the complaint to the ALJ that conducts the review. In cases related to pending reviews, the complaint generally is forwarded to the ALJ who is conducting the review.

(b) *Evaluating the acceptability of the complaint.* The ALJ assigned to the LCD review determines if the complaint is acceptable by confirming all of the following:

(1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a

complaint is acceptable, the ALJ assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)

(2) The complaint meets the requirements for a valid complaint in § 426.400 and does not challenge one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the ALJ determines that the complaint is unacceptable, the ALJ must provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the ALJ, the ALJ must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined unacceptable after one amendment, the beneficiary is precluded from filing again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the ALJ determines that the complaint (or amended complaint) is acceptable, the ALJ does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the complaint and informing the aggrieved party (or parties) of the docket number and the deadline for the contractor to produce the LCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to the applicable contractor and CMS.

(3) Requires CMS or the contractor to send a copy of the LCD record to the ALJ and all parties to the LCD review within 30 days of receiving the ALJ's letter, the copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an LCD*—(1) *Criteria for consolidation.* If a review is pending regarding a particular LCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the ALJ consolidates the complaints and conducts a consolidated LCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same LCD or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the ALJ's decision.

(2) *Decision to consolidate complaints.* If an ALJ decides to consolidate complaints, the ALJ does the following:

(i) Provides notification that the LCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each LCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints.* If an ALJ decides not to consolidate complaints, the ALJ conducts separate LCD reviews for each complaint.

[68 FR 63716, Nov. 7, 2003; 68 FR 65346, Nov. 19, 2003]

§ 426.415 CMS' role in the LCD review.

CMS may provide to the ALJ, and all parties to the LCD review, information identifying the person who represents the contractor or CMS, if necessary, in the LCD review process.

§ 426.416 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the LCD review.

Medicare MCOs and Medicaid State agencies have no role in the LCD review process. However, once the ALJ has issued its decision, the decision is made available to all Medicare MCOs and State agencies.

§ 426.417 Contractor's statement regarding new evidence.

(a) The contractor may review any new evidence that is submitted, regardless of whether the ALJ has stayed the proceedings, including but not limited to—

(1) New evidence submitted with the initial complaint;

(2) New evidence submitted with an amended complaint;

(3) New evidence produced during discovery;

(4) New evidence produced when the ALJ consults with scientific and clinical experts; and

(5) New evidence presented during any hearing.

(b) The contractor may submit a statement regarding whether the new evidence is significant under § 426.340, within such deadline as the ALJ may set.

§ 426.418 LCD record furnished to aggrieved party.

(a) *Elements of a contractor's LCD record furnished to the aggrieved party.* Except as provided in paragraph (b) of this section, the contractor's LCD record consists of any document or material that the contractor considered during the development of the LCD, including, but not limited to, the following:

(1) The LCD being challenged.

(2) Any medical evidence considered on or before the date the LCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(3) Comment and Response Document (a summary of comments received by the contractor concerning the draft LCD).

(4) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the LCD record not furnished to the aggrieved party.* The LCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.419 LCD record furnished to the ALJ.

The LCD record furnished to the ALJ includes the following:

(a) Documents included in § 426.418(a).

(b) Privileged information and proprietary data considered that must be filed with the ALJ under seal.

§ 426.420 Retiring or revising an LCD under review.

(a) A contractor may retire an LCD or LCD provision under review before the date the ALJ issues a decision regarding that LCD. Retiring an LCD or LCD provision under review has the same effect as a decision under § 426.460(b).

(b) A contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint through the reconsideration process before the date the ALJ issues a decision regarding that LCD. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under § 426.460(b).

(c) A contractor must notify the ALJ within 48 hours of—

(1) Retiring an LCD or LCD provision that is under review; or

(2) Issuing a revised version of the LCD that is under review.

(d) If the contractor issues a revised LCD, the contractor forwards a copy of the revised LCD to the ALJ.

(e) The ALJ must take the following actions upon receiving a notice that the contractor has retired or revised an LCD under review:

(1) If, before the ALJ issues a decision, the ALJ receives notice that the contractor has retired the LCD or revised the LCD to completely remove the provision in question, the ALJ must dismiss the complaint and inform the aggrieved party(ies) who sought the review that he or she or they receive individual claim review without the retired/withdrawn provision(s).

(2) If, before the ALJ issues a decision, the ALJ receives notice that the contractor has revised the LCD provision in question but has not removed it altogether, the ALJ must continue the review based on the revised LCD. In this case, the contractor must send a copy of the supplemental record to the ALJ and all parties. In that circumstance, the ALJ permits the aggrieved party to respond to the revised LCD and supplemental record.

§ 426.423 Withdrawing a complaint regarding an LCD under review.

(a) *Circumstance under which an aggrieved party may withdraw a complaint regarding an LCD.* An aggrieved party

who filed a complaint regarding an LCD may withdraw the complaint before the ALJ issues a decision regarding that LCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an LCD.* To withdraw a complaint regarding an LCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the ALJ (*see* § 426.400), CMS (if applicable), and the applicable contractor. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.403.

(c) *Actions the ALJ must take upon receiving a notice announcing the intent to withdraw a complaint regarding an LCD*—(1) *LCD reviews involving one aggrieved party.* If the ALJ receives a withdrawal notice regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing the complaint under § 426.444 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *LCD reviews involving joint complaints.* If the ALJ receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ issues a decision dismissing only that aggrieved party from the complaint under § 426.444. The ALJ continues the LCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated LCD reviews.* If the ALJ receives a notice from an aggrieved party who is part of a consolidated LCD review withdrawing a complaint regarding an LCD before the date the ALJ issued a decision regarding that LCD, the ALJ removes that aggrieved party from the consolidated LCD review and issues a decision dismissing that aggrieved party's complaint under § 426.444. The ALJ continues the LCD review if there are one or more aggrieved parties who does not withdraw from the joint complaint.

§ 426.425 LCD review.

(a) *Opportunity for the aggrieved party, after his or her review of the LCD record, to state why the LCD is not valid.* Upon receipt of the contractor's LCD record, the aggrieved party files a statement explaining why the contractor's LCD record is not complete, or not adequate to support the validity of the LCD under the reasonableness standard. This statement must be submitted to the ALJ and to the contractor, or CMS, as appropriate, within 30 days (or within the additional time as allowed by the ALJ for good cause shown) of the date the aggrieved party receives the contractor's LCD record.

(b) *Contractor response.* The contractor has 30 days after receiving the aggrieved party's statement to submit a response to the ALJ in order to defend the LCD.

(c) *ALJ evaluation.* (1) After the aggrieved party files a statement and the contractor responds, as described in § 426.425(a) and § 426.425(b), or the time for filing has expired, the ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the validity of the LCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process.

(3) If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, the ALJ permits discovery and the taking of evidence in accordance with § 426.432 and § 426.440 and evaluates the LCD in accordance with § 426.431.

(d) The process described in paragraphs (a), (b), and (c) of this section applies when an LCD record has been supplemented, except that discovery and the taking of evidence are not repeated. The period for the aggrieved party to file a statement begins when the aggrieved party receives the supplement.

§ 426.431 ALJ's review of the LCD to apply the reasonableness standard.

(a) *Required steps.* To review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard, an ALJ must:

(1) Confine the LCD review to the provision(s) of the LCD raised in the aggrieved party's complaint.

(2) Conduct a hearing, unless the matter can be decided on the written record.

(3) Close the LCD review record to the taking of evidence.

(4) Treat as precedential any previous Board decision under § 426.482 that involves the same LCD provison(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.447.

(b) *Optional steps*. The ALJ may do the following to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint:

(1) Consult with appropriate scientific or clinical experts concerning evidence.

(2) Consider any previous ALJ decision made under § 426.447 regarding the same provision(s) of the LCD under review and for the same clinical conditions.

(c) *Authority for ALJs in LCD reviews when applying the reasonableness standard*. In applying the reasonableness standard to a provision (or provisions) of an LCD, the ALJ must follow all applicable laws, regulations, rulings, and NCDs.

§ 426.432 Discovery.

(a) *General rule*. If the ALJ orders discovery, the ALJ must establish a reasonable timeframe for discovery.

(b) *Protective order*—(1) *Request for a protective order*. Any party receiving a discovery request may file a motion for a protective order before the date of production of the discovery.

(2) *The ALJ granting of a protective order*. The ALJ may grant a motion for a protective order if (s)he finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;

(ii) Is unduly costly or burdensome; or

(iii) Unduly delays the proceeding.

(c) *Types of discovery available*. A party may obtain discovery via a request for the production of documents, and/or via the submission of up to 10 written interrogatory questions, relating to a specific LCD.

(d) *Types of documents*. For the purpose of this section, the term ''documents'' includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained in this section is interpreted to require the creation of a document.

(e) *Types of discovery not available*. Requests for admissions, depositions, or any other forms of discovery, other than those permitted under paragraph (c) of this section, are not authorized.

(f) *Privileged information and proprietary data*. The ALJ must not, under any circumstance, order the disclosure of privileged information or proprietary data filed under seal without the consent of the party who possesses the right to protection of the information.

(g) *Notification*. The ALJ notifies all parties in writing when the discovery period closes.

§ 426.435 Subpoenas.

(a) *Purpose of a subpoena*. A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence authorized under § 426.440 at or before the hearing.

(b) *Filing a motion for a subpoena*. A party seeking a subpoena must file a written motion with the ALJ not less than 30 days before the date fixed for the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by the witnesses or documents and whether other evidence may establish without the use of a subpoena.

(c) *Response to a motion for a subpoena*. Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown*. The ALJ may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted.* If the ALJ grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the ALJ.

(2) Include the docket number and title of the LCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the ''Commissioner of Social Security'' shall be considered a reference to the ''Secretary.''

§ 426.440 Evidence.

(a) Except as provided in this part, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The ALJ must exclude evidence that (s)he determines is clearly irrelevant, immaterial, or unduly repetitive.

(c) The ALJ may accept privileged information or proprietary data, but must maintain it under seal.

(d) The ALJ may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The ALJ may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the ALJ or a party to the proceeding, or the reports will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the ALJ for good cause shown, all documents and other evidence offered or taken for the record are open to examination by all parties.

§ 426.444 Dismissals for cause.

(a) The ALJ may, at the request of any party, or on his or her own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a pre-hearing conference (the pre-hearing may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the ALJ without good cause shown.

(b) The ALJ must dismiss any complaint concerning LCD provision(s) if the following conditions exist:

(1) The ALJ does not have the authority to rule on that provision under § 426.405(d).

(2) The complaint is not timely. (*See* § 426.400(b).)

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an NCD. (*See* § 426.405, regarding the authority of the ALJ.)

(6) The contractor notifies the ALJ that the LCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (*See* § 426.423 for requirements related to withdrawing a complaint regarding an LCD under review.)

§ 426.445 Witness fees.

(a) A witness testifying at a hearing before an ALJ receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee.

Witness fees are paid by the party seeking to present the witness.

(b) If an ALJ requests expert testimony, the appropriate office overseeing the ALJ is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.446 Record of hearing.

The ALJ must ensure that all hearings are open to the public and are electronically, mechanically or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the ALJ relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.447 Issuance and notification of an ALJ's decision.

An ALJ must issue to all parties to the LCD review, within 90 days of closing the LCD review record to the taking of evidence, one of the following:

(a) A written decision, including a description of appeal rights.

(b) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

§ 426.450 Mandatory provisions of an ALJ's decision.

(a) *Findings*. An ALJ's decision must include one of the following:

(1) A determination that the provision of the LCD is valid under the reasonableness standard.

(2) A determination that the provision of the LCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the LCD and a rationale for the dismissal.

(4) A determination that the LCD record is complete and adequate to support the validity of the LCD provisions under the reasonableness standard.

(b) *Other information*. An ALJ's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the LCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the LCD was or was not valid based on the application of the reasonableness standard to the record before the ALJ, including the contractor's:

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. If proprietary or privileged data were submitted under seal, the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the ALJ's treatment of the sealed evidence must be prepared and kept under seal itself. If the ALJ decision is appealed to the Board, this statement must be provided to the Board under seal.

(6) A statement regarding appeal rights.

§ 426.455 Prohibited provisions of an ALJ's decision.

An ALJ's decision may not do any of the following:

(a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS or its contractors to establish a new or revised LCD.

(d) Review or evaluate an LCD other than the LCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an LCD, or deadlines for implementing these types of changes.

(f) Order or address how a contractor(s) must implement an LCD.

§ 426.457 Optional provisions of an ALJ's decision.

When appropriate, the ALJ may limit a decision holding invalid a specific provision(s) of an LCD to specific

clinical indications and for similar conditions.

§ 426.458 ALJ's LCD review record.

(a) *Elements of the ALJ's LCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the ALJ's LCD review record consists of any document or material that the ALJ compiled or considered during the LCD review, including, but not limited to, the following:

(1) The LCD complaint.

(2) The LCD and LCD record.

(3) The supplemental LCD record, if applicable.

(4) Transcripts of record.

(5) Any other relevant evidence gathered under § 426.440.

(6) The ALJ's decision.

(b) *Elements of the ALJ's LCD review record furnished to the Board under seal.* The ALJ's review record must include, under seal, any proprietary data or privileged information maintained under seal, and such data or information must not be included in the review record furnished to the public.

§ 426.460 Effect of an ALJ's decision.

(a) *Valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party or parties may appeal that (those) part(s) of the ALJ decision to the Board under § 426.465.

(b) *Not valid under the reasonableness standard.* If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) invalid under the reasonableness standard, and no appeal is filed by the contractor or CMS under § 426.465(b), the contractor, the M+C organization, or other Medicare managed care organization must provide the following—

(1) *Individual claim review.* (i) If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), and if the party's claim or appeal(s) was previously denied, the contractor, an M+C organization or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid.

(ii) If a revised LCD is issued, the contractor, the M+C organization, and any other Medicare managed care organization within the contractor's jurisdiction uses the revised LCD in reviewing claim or appeal submissions or request for services delivered or services performed on or after the effective date of the revised LCD.

(iii) If the aggrieved party who sought the review has not yet submitted a claim, the contractor adjudicates the claim without using the provision(s) of the LCD that the ALJ found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances is adjudicated without using the LCD provision(s) found invalid.

(2) *Coverage determination relief.* If neither the contractor nor CMS appeals the ALJ decision under § 426.425(b), the contractor implements the ALJ decision within 30 days. Any change in policy applies prospectively to requests for service or claims filed with dates of service after the implementation of the ALJ decision.

§ 426.462 Notice of an ALJ's decision.

After the ALJ has made a decision regarding an LCD complaint, the ALJ sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the time limit under which an appeal must be requested.

§ 426.463 Future new or revised LCDs.

The contractor may not reinstate an LCD provision(s) found to be unreasonable unless the contractor has a different basis (such as additional evidence) than what the ALJ evaluated.

§ 426.465 Appealing part or all of an ALJ's decision.

(a) *Circumstances under which an aggrieved party may appeal part or all of an ALJ's decision.* An aggrieved party (including one or more aggrieved parties

named in a joint complaint and an aggrieved party who is part of a consolidated LCD review) may appeal to the Board any part of an ALJ's decision that does the following:

(1) States that a provision of an LCD is valid under the reasonableness standard; or

(2) Dismisses a complaint regarding an LCD (except as prohibited in paragraph (b) of this section).

(b) *Circumstance under which a contractor or CMS may appeal part or all of an ALJ's decision.* A contractor or CMS may appeal to the Board any part of an ALJ's decision that states that a provision (or provisions) of an LCD is (are) unreasonable.

(c) *Stay of an implementation pending appeal.* (1) If an ALJ's decision finds a provision or provisions of an LCD unreasonable, an appeal by a contractor or CMS stays implementation as described under § 426.460(b) until the Board issues a final decision.

(2) The appeal request must be submitted to the Board in accordance with paragraph (e) of this section.

(d) *Circumstances under which an ALJ's decision may not be appealed.* An ALJ's decision dismissing a complaint is not subject to appeal in either of the following circumstances:

(1) The contractor has retired the LCD provision(s) under review.

(2) The aggrieved party who filed the complaint has withdrawn the complaint.

(e) *Receipt of the appeal by the Board.* Unless there is good cause shown, an appeal described in paragraphs (a) or (b) of this section must be filed with the Board within 30 days of the date the ALJ's decision was issued.

(f) *Filing an appeal.* (1) To file an appeal described in paragraph (a) of this section, an aggrieved party, who sought LCD review, a contractor, or CMS must send the following to the Board:

(i) The full names and addresses of the parties, including the name of the LCD.

(ii) The date of issuance of the ALJ's decision.

(iii) The docket number that appears on the ALJ's decision.

(iv) A statement identifying the part(s) of the ALJ's decision that are being appealed.

(2) If an appeal described in paragraph (a) of this section is filed with the Board later than the date described in paragraph (c) of this section, it must include a rationale stating why the Board must accept the late appeal.

(3) An appeal described in paragraph (a) of this section must include a statement explaining why the ALJ's decision should be reversed.

§ 426.468 Decision to not appeal an ALJ's decision.

(a) Failure to timely appeal without good cause shown waives the right to challenge any part(s) of the ALJ's decision under § 426.465.

(b) Unless the Board finds good cause shown for late filing, an untimely appeal is dismissed.

(c) If a party does not timely appeal any part(s) of the ALJ's decision on an LCD review to the Board, as provided in this subpart, then the ALJ's decision is final and not subject to further review.

§ 426.470 Board's role in docketing and evaluating the acceptability of appeals of ALJ decisions.

(a) *Docketing the appeal.* The Board does the following upon receiving an appeal of part or all of an ALJ's decision:

(1) Dockets the appeal either separately or with similar appeals.

(2) Assigns a docket number.

(b) *Evaluating the acceptability of the appeal.* The Board determines if the appeal is acceptable by confirming that the appeal meets all of the criteria in § 426.465.

(c) *Unacceptable appeal.* If the Board determines that an appeal is unacceptable, the Board must dismiss the appeal.

(d) *Acceptable appeal.* If the Board determines that an appeal is acceptable, the Board does the following:

(1) Sends a letter to the appellant to acknowledge that the appeal is acceptable, and informs them of the docket number.

(2) Forwards a copy of the appeal and the letter described in paragraph (d)(1)

of this section to all parties involved in the appeal.

(3) Requires the ALJ to send a copy of the ALJ's LCD review record (maintaining any sealed documents) to the Board and a copy of the public record to all parties involved in the appeal.

(e) *No participation as amicus curiae.* The Board may not allow participation by amicus participants in the review of an LCD.

§ 426.476 Board review of an ALJ's decision.

(a) *Review steps.* If the Board determines that an appeal is acceptable, the Board—

(1) Permits the party that did not file the appeal an opportunity to respond to the appeal;

(2) Hears oral argument (which may be held by telephone) if the Board determines that oral argument would be helpful to the Board's review of the ALJ decision;

(3) Reviews the LCD review record and the parties' arguments; and

(4) Issues a written decision either upholding, modifying, or reversing the ALJ decision, or remanding the case to the ALJ for further proceedings.

(b) *Standard of review.* (1) *In general.* The Board determines whether the ALJ decision contains any material error, including any failure to properly apply the reasonableness standard.

(2) If the ALJ erred in determining that the contractor's record was complete and adequate to support the validity of the LCD, the Board remands the case to the ALJ for discovery and the taking of evidence.

(3) If a party alleges a prejudicial error of procedure, and the Board determines that such an error was made, the Board may remand the case to the ALJ for further proceedings consistent with the Board decision or may take other appropriate steps to correct the procedural error.

(4) Harmless error is not a basis for reversing an ALJ decision.

(c) *Scope of review.* In reaching its conclusions, the Board is bound by applicable laws, regulations, and NCDs.

(d) *Dismissal as moot.* The Board dismisses an appeal by an aggrieved party of an ALJ decision finding that an LCD was valid if the contractor notifies the Board that it has retired the LCD or revised the LCD to remove the LCD provision in question.

§ 426.478 Retiring or revising an LCD during the Board's review of an ALJ's decision.

A contractor may retire or revise an LCD during the Board's review of an ALJ's decision using the same process described in § 426.420. If an LCD is retired or revised to remove completely the challenged provision(s), the aggrieved party who sought the review is entitled to individual claim review provided at § 426.488(b).

§ 426.480 Withdrawing an appeal of an ALJ's decision.

(a) *Withdrawal of an appeal of an ALJ's decision.* A party who filed an appeal of an ALJ's decision may withdraw the appeal before the Board issues a decision regarding the ALJ's decision.

(b) *Process of withdrawing an appeal of an ALJ's decision.* To withdraw an appeal of an ALJ's decision, the party who filed the appeal must send a written notice announcing the intent to withdraw to the Board and to any other party.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw an appeal of an ALJ's decision*—(1) *Appeals involving one aggrieved party, or initiated by CMS or a contractor.* If the Board receives a notice withdrawing an appeal of an ALJ's decision before the Board has issued its decision, the Board must issue a decision dismissing the appeal.

(2) *Appeals involving joint complaints.* If the Board receives a notice withdrawing an appeal from an aggrieved party who is named in a joint appeal before the Board issues its decision, the Board must issue a decision dismissing only that aggrieved party from the appeal. The Board must continue its review of the ALJ's decision for the remaining aggrieved party or parties.

§ 426.482 Issuance and notification of a Board decision.

The Board must issue a written decision, including a description of appeal rights, to all parties to the review of the ALJ decision.

§ 426.484 Mandatory provisions of a Board decision.

(a) *Findings.* A Board decision must include at least one of the following:

(1) A statement upholding the part(s) of the ALJ decision named in the appeal.

(2) A statement reversing the part(s) of the ALJ decision named in the appeal.

(3) A statement modifying the part(s) of the ALJ decision named in the appeal.

(4) A statement dismissing the appeal of an ALJ decision and a rationale for the dismissal.

(b) *Other information.* A Board decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the review of the ALJ decision.

(3) A summary of the ALJ's decision.

(4) A rationale for the basis of the Board's decision.

§ 426.486 Prohibited provisions of a Board decision.

A Board decision must not do any of the following:

(a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit to establish a new or revised LCD.

(d) Review or evaluate an LCD other than the LCD named in the ALJ's decision.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or system changes for an LCD or deadlines for implementing these changes.

(f) Order CMS or its contractors to implement an LCD in a particular manner.

§ 426.487 Board's record on appeal of an ALJ's decision.

(a) *Elements of the Board's LCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's LCD review record consists of any document or material that the Board compiled or considered during an LCD review, including, but not limited to, the following:

(1) The LCD complaint.

(2) The LCD and LCD record.

(3) The supplemental LCD record, if applicable.

(4) Transcripts of record.

(5) Any other relevant evidence gathered under § 426.440.

(6) The ALJ's decision.

(7) The Board's decision.

(b) *Elements of the Board's LCD appeal record furnished to the court under seal.* The Board's LCD review record must include, under seal, any proprietary data or privileged information submitted and reviewed in the LCD review process, and that data or information must not be included in the review record furnished to the public, but the information must be maintained, under seal, by the Board.

(c) *Protective order.* In any instance where proprietary data or privileged information is used in the LCD process and a court seeks to obtain or require disclosure of any proprietary data or privileged information contained in the LCD record, CMS or the Department will seek to have a protective order issued for that information, as appropriate.

§ 426.488 Effect of a Board decision.

(a) *The Board's decision upholds an ALJ decision that an LCD is valid or reverses an ALJ decision that an LCD is invalid.* If the Board's decision upholds the ALJ decision that an LCD is valid under the reasonableness standard or reverses an ALJ decision that an LCD is invalid, the contractor or CMS is not required to take any action.

(b) *The Board's decision upholds an ALJ determination that the LCD is invalid.* If the Board's decision upholds an ALJ determination that the LCD is invalid, then the contractor, the M+C organization, or other Medicare managed care organization implements the decision as described in § 426.460(b).

(c) *The Board's decision reverses a dismissal or an ALJ decision that the LCD is valid.* If the Board reverses an ALJ decision dismissing a complaint or holding that an LCD is valid without requiring discovery or the taking of evidence, the Board remands to the ALJ and the LCD review continues. If the Board reverses an ALJ decision holding that an LCD is valid that is reached after the ALJ has completed discovery

and the taking of evidence, the Board may remand the case to the ALJ for further proceedings, or the Board may find that the provision(s) of the LCD named in the complaint is (are) invalid under the reasonableness standard, and the contractor, the M+C organization, or other Medicare managed care organization provides the relief in § 426.460(b).

§ 426.489 Board remands.

(a) *Notice when case is remanded to the ALJ.* If the Board remands a case to the ALJ, the Board—

(1) Notifies each aggrieved party who sought the LCD review, through his or her representative or at his or her last known address, the contractor, and CMS of the Board's remand decision; and

(2) Explains why the case is being remanded and the specific actions ordered by the Board.

(b) *Action by an ALJ on remand.* An ALJ takes any action that is ordered by the Board and may take any additional action that is not inconsistent with the Board's remand order.

§ 426.490 Board decision.

A decision by the Board (other than a remand) constitutes a final agency action and is subject to judicial review. Neither the contractor nor CMS may appeal a Board decision.

Subpart E—Review of an NCD

§ 426.500 Procedure for filing an acceptable complaint concerning a provision (or provisions) of an NCD.

(a) *The complaint.* An aggrieved party may initiate a review of an NCD by filing a written complaint with the Department of Health and Human Services Departmental Appeals Board.

(b) *Timeliness of a complaint.* An NCD complaint is not considered timely unless it is filed with the Board within—

(1) 6 months of the written statement from each aggrieved party's treating physician, in the case of aggrieved parties who choose to file an NCD challenge before receiving the service; or

(2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an NCD challenge after receiving the service.

(c) *Components of a valid complaint.* A complaint must include the following:

(1) *Beneficiary-identifying information:*

(i) Name.

(ii) Mailing address.

(iii) State of residence, if different from mailing address.

(iv) Telephone number, if any.

(v) Health Insurance Claim number, if applicable.

(vi) Email address, if applicable.

(2) *If the beneficiary has a representative,* the representative's indetifying information must include the following:

(i) Name.

(ii) Address.

(iii) Telephone number.

(iv) E-mail address (if any)

(v) Copy of the written authorization to represent the beneficiary.

(3) *Treating physician written statement.* A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the NCD. This statement may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

(4) *NCD-identifying information:*

(i) Title of NCD being challenged.

(ii) The specific provision or provisions of the NCD adversely affecting the aggrieved party.

(5) *Aggrieved party statement.* A statement from the aggrieved party explaining what service is needed and why the aggrieved party thinks that the provision(s) of the NCD is (are) not valid under the reasonableness standard.

(6) *Clinical or scientific evidence.* (i) Copies of clinical or scientific evidence that supports the complaint and an explanation for why the aggrieved party thinks that this evidence shows that the NCD is not reasonable.

(ii) Any documents or portions of documents that include proprietary data must be marked ''proprietary data,'' and include a legal basis for that assertion.

(iii) Proprietary data submitted by a manufacturer concerning a drug or device for which the manufacturer has submitted information to the Food and

Drug Administration, must be considered and given substantive weight only when supported by an affidavit certifying that the submission contains true and correct copies of all data submitted by the manufacturer to the Food and Drug Administration in relation to that drug or device.

(d) *Joint complaints*—(1) *Conditions for a joint complaint.* Two or more aggrieved parties may initiate the review of an NCD by filing a single written complaint with the Board if all of the following conditions are met:

(i) Each aggrieved party named in the joint complaint has a similar medical condition or there are other bases for combining the complaints.

(ii) Each aggrieved party named in the joint complaint is filing the complaint in regard to the same provision(s) of the same NCD.

(2) *Components of a valid joint complaint.* A joint complaint must contain the following information:

(i) The beneficiary-identifying information described in paragraph (c)(1) of this section for each aggrieved party named in the joint complaint.

(ii) The NCD-identifying information described in paragraph (c)(2) of this section.

(iii) The documentation described in paragraphs (c)(3) and (c)(4) of this section.

(3) *Timeliness of a joint complaint.* Aggrieved parties, who choose to seek review of an NCD—

(i) Before receiving the service, must file with the Board a joint complaint within 6 months of the written statement from each aggrieved party's treating physician; or

(ii) After receiving the service, must file with the Board a complaint within 120 days of each aggrieved party's initial denial notice.

§ 426.503 Submitting new evidence once an acceptable complaint has been filed.

Once an acceptable complaint has been filed, the aggrieved party may submit additional new evidence without withdrawing the complaint until the Board closes the record.

§ 426.505 Authority of the Board.

(a) The Board conducts a fair and impartial hearing, avoids unnecessary delay, maintains order, and ensures that all proceedings are recorded.

(b) The Board defers only to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

(c) The Board has the authority to do any of the following:

(1) Review complaints by an aggrieved party (or aggrieved parties).

(2) Dismiss complaints that fail to comply with § 426.500.

(3) Set and change the date, time, and place of a hearing upon reasonable notice to the parties.

(4) Continue or recess a hearing for a reasonable period of time.

(5) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(6) Consult with scientific and clinical experts on its own motion, concerning clinical or scientific evidence.

(7) Set schedules for submission of exhibits and written reports of experts.

(8) Administer oaths and affirmations.

(9) Examine witnesses.

(10) Issue subpoenas requiring the attendance of witnesses at hearings as permitted by this part.

(11) Issue subpoenas requiring the production of existing documents before, and relating to, the hearing as permitted by this part.

(12) Rule on motions and other procedural matters.

(13) Stay the proceeding in accordance with § 426.340.

(14) Regulate the scope and timing of documentary discovery as permitted by this part.

(15) Regulate the course of a hearing and the conduct of representatives, parties, and witnesses.

(16) Receive, rule on, exclude, or limit evidence, as provided in this regulation.

(17) Take official notice of facts, upon motion of a party.

(18) Decide cases, upon the motion of a party, by summary judgment when there is no disputed issue of material fact.

(19) Conduct any conference, argument, or hearing in person or, upon agreement of the parties, by telephone, picture-tel, or any other means.

(20) Issue decisions.

(21) Exclude a party from an NCD review for failure to comply with a Board order or procedural request without good cause.

(22) Stay the proceedings for a reasonable time when all parties voluntarily agree to mediation or negotiation, and provide mediation services upon request.

(d) The Board does not have authority to do any of the following under this part:

(1) Conduct an LCD review or conduct LCD hearings, except as provided by § 426.465.

(2) Conduct an NCD review or conduct NCD hearings on its own motion or on the motion of a nonaggrieved party.

(3) Issue a decision based on any new evidence without following § 426.340, regarding procedures for review of new evidence.

(4) Review any decisions by CMS to develop a new or revised NCD.

(5) Conduct a review of any draft NCDs, coverage decision memoranda, or withdrawn NCDs.

(6) Conduct a review of the merits of an unacceptable NCD complaint as discussed in § 426.510.

(7) Conduct an NCD review of any policy that is not an NCD, as defined in § 400.202 of this chapter.

(8) Allow participation by individuals or entities other than—

(i) The aggrieved party and/or his or her representative;

(ii) CMS and/or the contractor;

(iii) Experts called by the parties or Board; or

(iv) Third parties with a clearly identifiable and substantial interest in the outcome of the dispute who have petitioned for and been granted permission by the Board to participate in the proceedings as *amicus curiae*.

(9) Compel the parties to participate in a mediation process or to engage in settlement negotiations.

(10) Deny a request for withdrawal of a complaint by an aggrieved party.

(11) Compel CMS to conduct studies, surveys, or develop new information to support an NCD record.

(12) Deny CMS the right to reconsider, revise, or withdraw an NCD.

(13) Subject to the timely filing requirements, deny an aggrieved party, CMS, or its contractor the right to appeal an ALJ decision.

(14) Find invalid applicable Federal statutes, regulations, or rulings.

(15) Enter a decision specifying terms to be included in an NCD.

§ 426.506 *Ex parte* contacts.

No party or person (except Board staff) communicates in any way with the Board on any substantive matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 426.510 Docketing and evaluating the acceptability of NCD complaints.

(a) *Docketing the complaint*. The Board does the following upon receiving a complaint regarding an NCD:

(1) Dockets the complaint.

(2) Determines whether the complaint is—

(i) The first challenge to a particular NCD; or

(ii) Related to a pending NCD review.

(3) Forwards the complaint to the Board member who conducts the review.

(b) *Evaluating the acceptability of the complaint*. The Board determines if the complaint is acceptable by confirming all of the following:

(1) The complaint is being submitted by an aggrieved party or, in the case of a joint complaint, that each individual named in the joint complaint is an aggrieved party. (In determining if a complaint is acceptable, the Board assumes that the facts alleged by the treating physician's documentation regarding the aggrieved party's (or parties') clinical condition are true.)

(2) The complaint meets the requirements for a valid complaint in § 426.500 and is not one of the documents in § 426.325(b).

(c) *Unacceptable complaint.* (1) If the Board determines that the complaint is unacceptable, the Board must provide the aggrieved party (or parties) one opportunity to amend the unacceptable complaint.

(2) If the aggrieved party (or parties) fail(s) to submit an acceptable amended complaint within a reasonable timeframe as determined by the Board, the Board must issue a decision dismissing the unacceptable complaint.

(3) If a complaint is determined to be unacceptable after one amendment, the beneficiary is precluded from filing again for 6 months after being informed that it is unacceptable.

(d) *Acceptable complaint.* If the Board determines that the complaint (or amended complaint) is acceptable, the Board does the following:

(1) Sends a letter to the aggrieved party (or parties) acknowledging the complaint and informing the aggrieved party (or parties) of the docket number and the deadline for CMS to produce the NCD record.

(2) Forwards a copy of the complaint, any evidence submitted in the complaint, and the letter described in paragraph (d)(1) of this section to CMS.

(3) Requires CMS to send a copy of the NCD record to the Board and all parties to the NCD review within 30 days of receiving the Board's letter, a copy of the complaint, and any associated evidence, subject to extension for good cause shown.

(e) *Consolidation of complaints regarding an NCD*—(1) *Criteria for condideration.* If a review is pending regarding a particular NCD provision(s) and no decision has been issued ending the review, and a new acceptable complaint is filed, the Board consolidates the complaints and conducts a consolidated NCD review if all of the following criteria are met:

(i) The complaints are in regard to the same provision(s) of the same NCD, or there are other bases for consolidating the complaints.

(ii) The complaints contain common questions of law, common questions of fact, or both.

(iii) Consolidating the complaints does not unduly delay the Board's decision.

(2) *Decision to consolidate complaint.* If the Board decides to consolidate complaints, the Board does the following:

(i) Provides notification that the NCD review is consolidated and informs all parties of the docket number of the consolidated review.

(ii) Makes a single record of the proceeding.

(iii) Considers the relevant evidence introduced in each NCD complaint as introduced in the consolidated review.

(3) *Decision not to consolidate complaints.* If the Board decides not to consolidate complaints, the Board conducts separate NCD reviews for each complaint.

(f) *Public notice of complaint and opportunity for interested parties to participate.* (1) If an acceptable complaint is the first complaint the Board has received challenging the particular NCD or provision, then the Board posts notice on its Web site that it has received the complaint, specifying a time period for requests to participate in the review process.

(2) If an acceptable complaint challenges an NCD provision when review is pending and no decision has been issued ending the review, the Board may supplement the public notice on its Web site and extend the time for participation requests if indicated.

(3) The Board may allow participation, in the manner and by the deadlines established by the Board, when an NCD is being challenged and the Board decides that—

(i) The *amicus* participant has a clearly identifiable and substantial interest in the outcome of the dispute;

(ii) Participation would clarify the issues or otherwise be helpful in resolution of the dispute;

(iii) Participation does not result in substantial delay; and

(iv) The petition for participation meets the criteria in § 426.513.

§ 426.513 Participation as *amicus curiae.*

(a) *Petition for participation.* Any person or organization that wishes to participate as *amicus curiae* must timely file with the Board a petition that concisely states—

(1) The petitioner's interest in the hearing;

(2) Who will represent the petitioner; and

(3) The issues on which the petitioner intends to present argument.

(b) *The nature of the proposed amicus participation.* An *amicus curiae* is not a party to the hearing but may participate by—

(1) Submitting a written statement of position to the Board before the beginning of the hearing;

(2) Presenting a brief oral statement or other evidence at the hearing, at the point in the proceedings specified by the Board; and

(3) Submitting a brief or a written statement when the parties submit briefs.

(c) *Service by amicus curiae.* Serving copies of any briefs or written statements on all parties.

§ 426.515 CMS' role in making the NCD record available.

CMS will provide a copy of the NCD record (as described in § 426.518) to the Board and all parties to the NCD review within 30 days of the receipt of the Board's order.

§ 426.516 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the NCD review process.

Medicare MCOs and Medicaid State agencies may participate in the NCD review process only if they meet the *amicus* participant criteria listed in § 426.510(f)(3) and § 426.513.

§ 426.517 CMS' statement regarding new evidence.

(a) CMS may review any new evidence that is submitted, regardless of whether the Board has stayed the proceedings, including but not limited to new evidence:

(1) Submitted with the initial complaint;

(2) Submitted with an amended complaint;

(3) Produced during discovery;

(4) Produced when the Board consults with scientific and clinical experts; and

(5) Presented during any hearing.

(b) CMS may submit a statement regarding whether the new evidence is significant under § 426.340, by a deadline set by the Board.

§ 426.518 NCD record furnished to the aggrieved party.

(a) *Elements of the NCD record furnished to the aggrieved party.* Except as provided in paragraph (b) of this section, the NCD record consists of any document or material that CMS considered during the development of the NCD, including, but not limited to, the following:

(1) The NCD being challenged.

(2) Any medical evidence considered on or before the date the NCD was issued, including, but not limited to, the following:

(i) Scientific articles.

(ii) Technology assessments.

(iii) Clinical guidelines.

(iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.

(v) MCAC transcripts.

(3) Public comments received during the notice and comment period.

(4) Coverage decision memoranda.

(5) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the NCD record not furnished to the aggrieved party.* The NCD record furnished to the aggrieved party does not include the following:

(1) Proprietary data or privileged information.

(2) Any new evidence.

§ 426.519 NCD record furnished to the Board.

The NCD record furnished to the Board includes—

(a) Documents included in § 426.518(a); and

(b) Privileged information and proprietary data considered that must be filed with the Board under seal.

§ 426.520 Withdrawing an NCD under review or issuing a revised or reconsidered NCD.

(a) CMS may withdraw an NCD or NCD provision under review before the date the Board issues a decision regarding that NCD. Withdrawing an NCD or NCD provision under review has the same effect as a decision under § 426.560(b).

(b) CMS may revise an NCD under review to remove or amend the NCD provision listed in the complaint through the reconsideration process before the date the Board issues a decision regarding that NCD. Revising an NCD under review to remove the NCD provision in question has the same effect as a decision under § 426.560(b).

(c) CMS must notify the Board within 48 hours of—

(1) Withdrawing an NCD or NCD provision that is under review; or

(2) Issuing a revised or reconsidered version of the NCD that is under review.

(d) If CMS issues a revised or reconsidered NCD, CMS forwards a copy of the revised/reconsidered NCD to the Board.

(e) The Board must take the following actions upon receiving a notice that CMS has withdrawn or revised/reconsidered an NCD under review:

(1) If, before the Board issues a decision, the Board receives notice that CMS has withdrawn the NCD or revised the NCD to completely remove the provision in question, the Board must dismiss the complaint and inform the aggrieved party (ies) who sought the review that he or she or they will receive individual claim review without the retired/withdrawn provisions.

(2) If, before the Board issues a decision, the Board receives notice that CMS has revised the NCD provision in question but has not removed it altogether, the Board must continue the review based on the revised NCD. In this case, CMS must send a copy of the supplemental record to the Board and all parties. In that circumstance, the Board permits the aggrieved party to respond to the revised NCD and the supplemental record.

§ 426.523 Withdrawing a complaint regarding an NCD under review.

(a) *Circumstance under which an aggrieved party withdraws a complaint regarding an NCD.* An aggrieved party who filed a complaint regarding an NCD may withdraw the complaint before the Board issues a decision regarding that NCD. The aggrieved party may not file another complaint concerning the same coverage determination for 6 months.

(b) *Process for an aggrieved party withdrawing a complaint regarding an NCD.* To withdraw a complaint regarding an NCD, the aggrieved party who filed the complaint must send a written withdrawal notice to the Board (*see* § 426.500) and CMS. Supplementing an acceptable complaint with new evidence does not constitute a withdrawal of a complaint, as described in § 426.503.

(c) *Actions the Board must take upon receiving a notice announcing the intent to withdraw a complaint regarding an NCD*—(1) *NCD reviews involving one aggrieved party.* If the Board receives a withdrawal notice regarding an NCD before the date the Board issued a decision regarding that NCD, the Board issues a decision dismissing the complaint under § 426.544 and informs the aggrieved party that he or she may not file another complaint to the same coverage determination for 6 months.

(2) *NCD reviews involving joint complaints.* If the Board receives a notice from an aggrieved party who is named in a joint complaint withdrawing a complaint regarding an NCD before the date the Board issued a decision regarding that NCD, the Board issues a decision dismissing only that aggrieved party from the complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

(3) *Consolidated NCD reviews.* If the Board receives a notice from an aggrieved party who is part of a consolidated NCD review withdrawing a complaint regarding an NCD before the date the Board issued a decision regarding that NCD, the Board removes that aggrieved party from the consolidated NCD review and issues a decision dismissing that aggrieved party's complaint under § 426.544. The Board continues the NCD review if there is one or more aggrieved party who does not withdraw from the joint complaint.

§ 426.525 NCD review.

(a) *Opportunity for the aggrieved party after his or her review of the NCD record to state why the NCD is not valid.* Upon receipt of the NCD record, the aggrieved party files a statement explaining why the NCD record is not complete, or not adequate to support the

validity of the NCD under the reasonableness standard. This statement must be submitted to the Board and CMS, within 30 days (or within additional time as allowed by the Board for good cause shown) of the date the aggrieved party receives the NCD record.

(b) *CMS response.* CMS has 30 days, after receiving the aggrieved party's statement, to submit a response to the Board in order to defend the NCD.

(c) *Board evaluation.* (1) After the aggrieved party files a statement and CMS responds as described in § 426.525(a) and § 426.525(b), or the time for filing has expired, the Board applies the reasonableness standard to determine whether the NCD record is complete and adequate to support the validity of the NCD.

(2) Issuance of a decision finding the record complete and adequate to support the validity of the NCD ends the review process.

(3) If the Board determines that the NCD record is not complete and adequate to support the validity of the NCD, the Board permits discovery and the taking of evidence in accordance with § 426.532 and § 426.540, and evaluate the NCD in accordance with § 426.531.

(d) The process described in paragraphs (a), (b), and (c) of this section applies when an NCD record has been supplemented, except that discovery and the taking of evidence is not repeated. The period for the aggrieved party to file a statement begins when the aggrieved party receives the supplement.

§ 426.531 Board's review of the NCD to apply the reasonableness standard.

(a) *Required steps.* The Board must do the following to review the provision(s) listed in the aggrieved party's complaint based on the reasonableness standard:

(1) Confine the NCD review to the provision(s) of the NCD raised in the aggrieved party's complaint.

(2) Conduct a hearing unless the matter can be decided on the written record.

(3) Close the NCD review record to the taking of evidence.

(4) Treat as precedential any previous Board decision made under § 426.547 that involves the same NCD provision(s), same specific issue and facts in question, and the same clinical conditions.

(5) Issue a decision as described in § 426.547.

(b) *Optional steps.* The Board may consult with appropriate scientific or clinical experts concerning clinical and scientific evidence to apply the reasonableness standard to the provision(s) listed in the aggrieved party's complaint.

(c) *Authority for the Board in NCD reviews when applying the reasonableness standard.* In applying the reasonableness standard to a provision (or provisions) of an NCD, the Board must follow all applicable laws and regulations, as well as NCDs other than the one under review.

§ 426.532 Discovery.

(a) *General rule.* If the Board orders discovery, the Board must establish a reasonable timeframe for discovery.

(b) *Protective order*—(1) *Request for a protective order.* Any party receiving a discovery request may file a motion for a protective order before the date of production of the discovery.

(2) *The Board granting of a protective order.* The Board may grant a motion for a protective order if it finds that the discovery sought—

(i) Is irrelevant or unduly repetitive;

(ii) Is unduly costly or burdensome; or

(iii) Will unduly delay the proceeding.

(c) *Types of discovery available.* A party may obtain discovery via a request for the production of documents, and/or via the submission of up to 10 written interrogatory questions, relating to a specific NCD.

(d) *Types of documents.* For the purpose of this section, the term documents includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained in this section will be interpreted to require the creation of a document.

(e) *Types of discovery not available.* Requests for admissions, depositions, or any other forms of discovery, other than those permitted under paragraph (c) of this section, are not authorized.

(f) *Privileged information or proprietary data.* The Board must not under any circumstances order the disclosure of privileged information or proprietary data filed under seal without the consent of the party who possesses the right to protection of the information.

(g) *Notification.* The Board notifies all parties in writing when the discovery period will be closed.

§ 426.535 Subpoenas.

(a) *Purpose of a subpoena.* A subpoena requires the attendance of an individual at a hearing and may also require a party to produce evidence authorized under § 426.540 at or before the hearing.

(b) *Filing a motion for a subpoena.* A party seeking a subpoena must file a written motion with the Board not less than 30 days before the date fixed for the hearing. The motion must do all of the following:

(1) Designate the witnesses.

(2) Specify any evidence to be produced.

(3) Describe the address and location with sufficient particularity to permit the witnesses to be found.

(4) State the pertinent facts that the party expects to establish by witnesses or documents and state whether those facts could be established by evidence other than by the use of a subpoena.

(c) *Response to a motion for a subpoena.* Within 15 days after the written motion requesting issuance of a subpoena is served on all parties, any party may file an opposition to the motion or other response.

(d) *Extension for good cause shown.* The Board may modify the deadlines specified in paragraphs (b) and (c) of this section for good cause shown.

(e) *Motion for a subpoena granted.* If the Board grants a motion requesting issuance of a subpoena, the subpoena must do the following:

(1) Be issued in the name of the presiding Board member.

(2) Include the docket number and title of the NCD under review.

(3) Provide notice that the subpoena is issued according to sections 1872 and 205(d) and (e) of the Act.

(4) Specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) *Delivery of the subpoena.* The party seeking the subpoena serves it by personal delivery to the individual named, or by certified mail return receipt requested, addressed to the individual at his or her last dwelling place or principal place of business.

(g) *Motion to quash a subpoena.* The individual to whom the subpoena is directed may file with the Board a motion to quash the subpoena within 10 days after service.

(h) *Refusal to obey a subpoena.* The exclusive remedy for contumacy by, or refusal to obey, a subpoena duly served upon any person is specified in section 205(e) of the Act (42 U.S.C. 405(e)) except that any reference to the ''Commissioner of Social Security'' shall be considered a reference to the ''Secretary.''

§ 426.540 Evidence.

(a) Except as provided in this part, the Board is not bound by the Federal Rules of Evidence. However, the Board may apply the Federal Rules of Evidence when appropriate, for example, to exclude unreliable evidence.

(b) The Board must exclude evidence that it determines is clearly irrelevant or immaterial, or unduly repetitive.

(c) The Board may accept privileged information or proprietary data, but must maintain it under seal.

(d) The Board may permit the parties to introduce the testimony of expert witnesses on scientific and clinical issues, rebuttal witnesses, and other relevant evidence. The Board may require that the testimony of expert witnesses be submitted in the form of a written report, accompanied by the curriculum vitae of the expert preparing the report.

(e) Experts submitting reports must be available for cross-examination at an evidentiary hearing upon request of the Board or a party to the proceeding, or the report will be excluded from the record.

(f) Except as set forth in paragraph (c) of this section or unless otherwise ordered by the Board for good cause shown, all documents and other evidence offered or taken for the record is open to examination by all parties.

§ 426.544 Dismissals for cause.

(a) The Board may, at the request of any party, or on its own motion, dismiss a complaint if the aggrieved party fails to do either of the following:

(1) Attend or participate in a prehearing conference (the prehearing may be conducted by telephone) or hearing without good cause shown.

(2) Comply with a lawful order of the Board without cause shown.

(b) The Board must dismiss any complaint concerning NCD provision(s) if the following conditions exist:

(1) The Board does not have the authority to rule on that provision under § 426.505(d).

(2) The complaint is not timely. (*See* § 426.500(b)).

(3) The complaint is not filed by an aggrieved party.

(4) The complaint is filed by an individual who fails to provide an adequate statement of need for the service from the treating physician.

(5) The complaint challenges a provision or provisions of an LCD except as provided in § 426.476, regarding the Board's review of an ALJ decision. (*See* § 426.505, regarding the authority of the Board.)

(6) CMS notifies the Board that the NCD provision(s) is (are) no longer in effect.

(7) The aggrieved party withdraws the complaint. (*See* § 426.523, for requirements for withdrawing a complaint regarding an NCD under review.)

§ 426.545 Witness fees.

(a) A witness testifying at a hearing before the Board receives the same fees and mileage as witnesses in Federal district courts of the United States. If the witness qualifies as an expert, he or she is entitled to an expert witness fee. Witness fees are paid by the party seeking to present the witness.

(b) If the Board requests expert testimony, the Board is responsible for paying all applicable fees and mileage, unless the expert waives payment.

§ 426.546 Record of hearing.

The Board must ensure that all hearings are open to the public and are electronically, mechanically, or stenographically reported. Except for privileged information and proprietary data that are filed under seal, all evidence upon which the Board relies for decision must be admitted into the public record. All medical reports, exhibits, and any other pertinent document, either in whole or in material part, must be offered, marked for identification, and retained in the case record.

§ 426.547 Issuance, notification, and posting of a Board's decision.

The Board must do the following:

(a) Issue to all parties to the NCD review, within 90 days of closing the NCD review record to the taking of evidence, one of the following:

(1) A written decision, including a description of appeal rights.

(2) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

(b) Make the decision available at the HHS Medicare Internet site. The posted decision does not include any information that identifies any individual, provider of service, or supplier.

§ 426.550 Mandatory provisions of the Board's decision.

(a) *Findings*. The Board's decision must include one of the following:

(1) A determination that the provision of the NCD is valid under the reasonableness standard.

(2) A determination that the provision of the NCD is not valid under the reasonableness standard.

(3) A statement dismissing the complaint regarding the NCD, and a rationale for the dismissal.

(4) A determination that the LCD or NCD record is complete and adequate to support the validity of the LCD or NCD provisions under the reasonableness standard.

(b) *Other information*. The Board's decision must include all of the following:

(1) The date of issuance.

(2) The docket number of the NCD review.

(3) A statement as to whether the aggrieved party has filed a claim for the service(s) named in the complaint, the date(s)-of-service, and the disposition, if known.

(4) A basis for concluding that the NCD was or was not valid based on the

application of the reasonableness standard to the record before the Board, including CMS':

(i) Findings of fact.

(ii) Interpretations of law.

(iii) Applications of fact to law.

(5) A summary of the evidence reviewed. Where proprietary or privileged data were submitted under seal, the decision must state whether the data were material and what role they played in the determination, but without disclosing the substance or contents of the evidence under seal. A separate statement of the rationale for the Board's treatment of the sealed evidence must be prepared and kept under seal itself. If the Board decision is appealed to the court, this statement must be provided to the court, under seal.

(6) A statement regarding the right to judicial review.

§ 426.555 Prohibited provisions of the Board's decision.

The Board's decision may not do any of the following:

(a) Order CMS to add any language to a provision or provisions of an NCD.

(b) Order CMS or its contractors to pay a specific claim.

(c) Set a time limit for CMS to establish a new or revised NCD.

(d) Review or evaluate an NCD other than the NCD under review.

(e) Include a requirement for CMS or its contractors that specifies payment, coding, or systems changes for an NCD, or deadlines for implementing these types of changes.

(f) Order or address how CMS implements an NCD.

§ 426.557 Optional provisions of the Board's decision.

When appropriate, the Board may limit a decision holding invalid a specific provision(s) of an NCD to specific clinical indications and for similar conditions.

§ 426.560 Effect of the Board's decision.

(a) *Valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) valid under the reasonableness standard, the aggrieved party may challenge the final agency action in Federal court.

(b) *Not valid under the reasonableness standard.* If the Board finds that the provision (or provisions) of an NCD named in the complaint is (are) invalid under the reasonableness standard, then CMS instructs its contractor, M+C organization, or other Medicare managed care organization to provide the following—

(1) *Individual claim review.* (i) If the aggrieved party's claim/appeal(s) was previously denied, the contractor, an M+C organization, or another Medicare managed care organization must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(ii) If a revised NCD is issued, contractors, M+C organizations, and other Medicare managed care organizations must use the revised NCD in reviewing claim/appeal submissions or request for services delivered or services performed on or after the effective date of the revised NCD.

(iii) If the aggrieved party who sought review has not yet submitted a claim, the contractor must adjudicate the claim without using the provision(s) of the NCD that the Board found invalid.

(iv) In either case, the claim and any subsequent claims for the service provided under the same circumstances, must be adjudicated without using the NCD provision(s) found invalid.

(2) *Coverage determination relief.* Within 30 days, CMS implements the Board decision. Any change in policy is applied prospectively to requests for service or claims filed with dates of service after the implementation of the Board decision.

§ 426.562 Notice of the Board's decision.

After the Board has made a decision regarding an NCD complaint, the Board sends a written notice of the decision to each party. The notice must—

(a) State the outcome of the review; and

(b) Inform each party to the determination of his or her rights to seek further review if he or she is dissatisfied with the determination, and the

time limit under which an appeal must be requested.

§ 426.563 Future new or revised or reconsidered NCDs.

CMS may not reinstate an NCD provision(s) found to be unreasonable unless CMS has a different basis (such as additional evidence) than what the Board evaluated.

§ 426.565 Board's role in making an LCD or NCD review record available.

Upon a request from a Federal Court, the Board must provide to the Federal Court a copy of the Board's LCD or NCD review record (as described in § 426.587).

§ 426.566 Board decision.

A decision by the Board constitutes a final agency action and is subject to judicial review. CMS may not appeal a Board decision.

§ 426.587 Record for appeal of a Board NCD decision.

(a) *Elements of the Board's NCD review record furnished to the public.* Except as provided in paragraph (b) of this section, the Board's NCD review record consists of any document or material that the Board compiled or considered during an NCD review, including, but not limited to, the following:

(1) The NCD complaint.

(2) The NCD and NCD record.

(3) The supplemental NCD record, if applicable.

(4) Transcripts of record.

(5) Any other evidence relevant gathered under § 426.540.

(6) The Board's decision.

(b) *Documents excluded from the NCD review record furnished to the court.* The NCD review record furnished to the court maintains the seal on privileged information or proprietary data that is maintained under seal by the Board. In the event a court seeks to obtain or requires disclosure of any documents excluded from the NCD record as privileged information or proprietary data, CMS or the Department seeks to have a protective order issued for those documents, as appropriate.

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

Material Approved for Incorporation by Reference
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Material Approved for Incorporation by Reference

(Revised as of October 1, 2005)

The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 CFR part 51 the incorporation by reference of the following publications. This list contains only those incorporations by reference effective as of the revision date of this volume. Incorporations by reference found within a regulation are effective upon the effective date of that regulation. For more information on incorporation by reference, see the preliminary pages of this volume.

42 CFR (PARTS 400–429)

CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

	42 CFR
American Hospital Association	
Available from: Centers for Medicare and Medicaid Services, Office of Management and Budget, Division of Communication Services, Printing and Publishing Branch, Gwynn Oak Bldg., Baltimore, MD 21235	
Chart of Accounts for Hospitals (1973 Ed.)	405.415(b)(7)(i)
American Lung Association	
(Formerly National Tuberculosis Association)	
1740 Broadway, New York, NY 10019	
Diagnostic Standards and Classification of Tuberculosis (1974 Ed.)	405.1039(b)(2)
American National Standards Institute	
25 West 43rd Street, Fourth floor, New York, NY 10036 Telephone: (212) 642-4900	
ANSI A117.1–1971 Specifications for Making Buildings and Facilities Accessible to and Usable by Physically Handicapped People.	405.1134(c)
American Psychiatric Association	
Division of Publications and Marketing, 1400 K Street NW., Washington, DC 20005	
Diagnostic and Statistical Manual of Mental Disorders, 1980 (3rd Ed.).	405.243(b); 405.1037(a)(12)
Association for the Advancement of Medical Instrumentation	
3330 Washington Blvd., Arlington, VA 22201–4598	
ASNI/AAMI RD5–1992, Hemodialysis Systems, second edition	405.2150(a); 405.2140(a)
Recommended Practice for Reuse of Hemodialyzers	405.2150
National Academy of Sciences	
Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418	
Recommended Dietary Allowances Current Edition, 1980 (9th Ed.)	405.1025(c)(2)
National Fire Protection Association (NFPA)	
1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269–9101	
NFPA 101, Life Safety Code (2000 Edition)	403.744; 416.44; 418.100

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VIII Office of Special Counsel (Parts 1800—1899)

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XI Armed Forces Retirement Home (Part 2100)

XIV Federal Labor Relations Authority, General Counsel of the Federal Labor Relations Authority and Federal Service Impasses Panel (Parts 2400—2499)

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List of CFR Sections Affected

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402.105 (a) revised; (d)(3), (4) and (g) added; eff. 10–29–01 49546
402.107 (b)(8) revised; eff. 10–29–01 49546
405.520 (c) revised; eff. 10–29–01 49547
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405.535 Heading revised; introductory text amended 55328
405.2175 Added 33030
405.2468 (f)(6)(ii)(D) revised 39932
410 Technical correction 13020, 13021, 16607
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410.26 (a) and (b) redesignated as (b) and (c); new (a) and (c) heading added 55328
410.28 (f) added 58809
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410.37 (d), (e)(2) and (g) revised; (e)(3) added 55329
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412.29 Introductory text revised; eff. 1–1–02 41387
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411.54 (c) and (d) revised 43942
411.354 Regulation at 66 FR 958 effective date delayed 20347
(d)(1) eff. date delayed in part to 7–7–04 74491
412 Technical correction 22268, 57732
Regulation at 68 FR 34122 corrected 41860
412.4 (b), (c) and (d) revised; (f)(1) amended 45469
412.20 (b) redesignated as (b)(1); (b)(2) added 45698
412.22 (h)(3)(ii) revised 10988
(h)(2) introductory text revised; (h)(6) added 34162
(e)(5)(i) amended; (f) revised 45469
(h)(2) introductory text revised; (h)(6) removed; (h)(7) added 45698
412.23 (e)(3)(ii) and (iii) revised 45469
412.25 (e)(4) introductory text amended 45469
(e)(2) introductory text revised; (e)(5) added 45698
412.29 (a)(2) revised 45699
412.30 (b)(3) and (d)(2)(i) revised 45699
412.84 (h) revised; (i), (j) and (k) redesignated as (j), (k) and (l); new (i) and (m) added; new (k) and (l) amended 34515
412.87 (b)(3) revised 45469
(b)(3) correctly designated 47637
412.105 (a)(1) introductory text, (i), (f)(1)(v) and (vi) amended; (b) and (f)(1)(x) revised 45470
412.106 (a)(1)(ii) and (b)(4)(i) revised 45470
412.112 (d) added 45470
412.115 (c) revised 67960
412.116 (e) amended 34515
(e) revised 45470
412.230 (e)(2)(ii)(A) revised 45470
412.278 (f)(2)(i) revised 45471

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412.503 Amended 34162
412.523 (c)(3) and (d)(3) revised 34162
412.525 (a) revised 34163
(a)(4) revised 34515
412.529 (c)(1) introductory text revised; (c)(4) redesignated as (c)(5) and amended; new (c)(4) added 34163
(c)(5) revised 34515
412.535 Revised 34163
412.541 (d)(1) amended 10988
412.602 Amended 45699
412.604 (a)(2) introductory text revised 45699
412.608 Revised 45699
412.610 (c)(1)(i)(C) revised 45699
412.614 (a) introductory text revised; (a)(3) and (e) added 45699
412.624 (c), (d),(e)(1) and (4) revised 45699
413 Technical correction 22268, 55882, 57732, 58756
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413.24 (f)(4)(i) through (v) revised 50721
413.65 (a)(1)(ii)(D) revised 46070
(g) introductory text added; (g)(1) revised; eff. 11–10–03 53261
413.70 (b)(2)(iii) introductory text revised 45471
413.85 (d)(1)(iii) and (g)(3) added; (h)(3) revised 45471
413.86 (b) and (g)(1) amended; (f) introductory text, (g)(4) introductory text, (iv), (5) introductory text, (6)(i)(D), (E), (7), (12) introductory text, (i), (ii) introductory text, (A), (B)(*1*)(*i*), (iii), (iv) introductory text, (A) and (iv)(B)(*1*) revised; (i) and (j) redesignated as (j) and (k); (f)(4)(iv), (g)(5)(vii) and new (i) added 45471
(k) correctly redesignated as (l) 57733
413.337 (d)(2) revised 46070
413.345 Amended 46071
413.355 Added 67960
414 Policy statement 9567
Technical correction 32400
414.22 (b)(6)(iii) revised 63261
414.46 (e), (f) and (g) redesignated as (f), (g) and (h); new (e) added 63261
414.605 Amended 67963
414.610 (c)(3) and (5) revised 67963

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416 Amublatory Surgical Centers list of covered procedures 15268
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416.44 (b)(1) and (3) revised; (b)(4) added 1385
417.479 (g)(2)(ii) amended; (h) heading, (1), (2), and (3) introductory text revised 50855
418.100 (d)(1), (3), and (4) revised 1386
419 Technical correction 6636
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Regulation at 68 FR 63398 corrected 75442
422 Technical correction 20349
422.2 Amended 50855
422.50 (a)(2) revised 50855
422.74 (d)(1)(ii) and (4) revised 50855
422.101 (b)(3) revised; (c) added 50856
422.106 Heading, (a) introductory text, (1), (2), and (b) introductory text revised; (c) added 50856
422.109 Revised 50856
422.111 (f)(8)(iii) added 50857
422.133 Added 50857
422.152 (f)(4) added 50857
422.202 (a)(4) revised 50857
422.210 (a) and (b) introductory text revised 50858
422.250 (a)(1) revised; (a)(2)(i)(B) redesignated as (a)(2)(i)(C); new (a)(2)(i)(B) added 50858
422.256 (b) revised 50858
422.266 (a) introductory text and (c) revised 50858
422.312 (d) redesignated as (e); new (d) added 50858
422.521 Added 50858
422.561 Amended 16667
422.564 Revised (OMB number pending) 16667
422.566 (c) revised 50859
422.618 (c) revised 50859
422.619 (c) revised 50859
422.620 Revised (OMB number pending) 16667
422.624 Added (OMB number pending) 16667
422.626 Added (OMB number pending) 16667
422.756 (f)(2) and (3) revised 50859
422.758 Introductory text, (a) and (b) redesignated as (a) introductory text, (1) and (2); new (b) added 50859

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424.32 (d) added; interim; eff. 10–16–03 48813
426 Added 63716
426.10 (a) corrected 65346

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403 Application deadline 69536
403.744 (a) and (c) revised 49240
403.746 (c) added 66419
403.764 Added 66419
403.766 Added 66419
403.768 Added 66419
403.770 Added 66419
405 Technical correction 35527
405.207 (b) revised 66420
405.378 (b)(2) revised 45607
405.400 Amended; interim 1116
405.517 (a) text redesignated as (a)(1) and amended; (a)(2) added; interim 1116
(a)(3) added 66420
405.1200—405.1208 (Subpart J) Added 69264
406.12 (e)(2) introductory text and (i) revised; eff. 11–23–04 57224
409.20 (c) introductory text revised 35529
410 Technical corrections 15729
410.1 (a)(6) added 66420
410.10 (y) added 66420
410.16 Added 66420
410.17 Added 66421
410.18 Added 66421
410.26 (c) revised 66421
410.32 (b)(2)(iii) revised 66421
410.59 (a) introductory text, (3)(ii), (b) heading and (c)(2) revised; (a)(3)(iii) and (e)(1)(iii) added 66421
410.60 (a) introductory text, (3)(ii), (b) heading and (c)(2) revised; (a)(3)(iii) and (e)(1)(iii) added 66422
410.62 (a) introductory text, (2)(i), (iii), (3), (b) and (c) revised 66422
410.63 (b) heading revised; (c) added 66422
410.78 (a)(4) and (b) introductory text revised 66423
410.160 (f) revised 66423
411 Technical correction; interim; eff. 7–26–04 17933

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411.15 (a)(1) revised; (k)(11) added 66423
411.24 (m)(2)(ii) and (iii) revised 45607
411.350—411.361 (Subpart J) Revised; interim; eff. 7–26–04 16126
411.354 (d)(1) eff. date delayed in part to 7-26-04 35529
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411.372 Added; interim 57227
411.373 Added; interim 57227
411.375 Added; interim 57228
411.377 Added; interim 57229
411.378 Added; interim 57229
411.379 Added; interim 57229
411.380 Added; interim 57229
411.382 Added; interim 57229
411.384 Added; interim 57230
411.386 Added; interim 57230
411.387 Added; interim 57230
411.388 Added; interim 57230
411.389 Added; interim 57230
411.404 (b) revised 66423
412 Authority citation revised 66976
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412.1 (a)(2), (3), (b)(12) and (13) redesignated as (a)(3), (4), (b)(13) and (14); new (a)(2) and (b)(12) added; new (b)(13) and (14) amended 66976
412.2 (b)(3) added 49240
412.4 (d) revised 49240
412.20 (a) revised; (b), (c) and (d) redesignated as (c), (d) and (e); new (b) added 66976
412.22 (a) amended; (e) revised; (h)(6) added 49240
(e)(1) introductory text corrected 60252
(b) revised 66976
412.23 (e)(3) and (4) revised 25720
(b)(2) revised 25775
(a)(1) and (2) redesignated as (a)(2) and (3); new (a)(1) added; (b) introductory text and (9) amended; (e) introductory text revised 66976
412.25 (g) added 49241
(a) introductory text revised 66976
412.27 Introductory text revised; (a) amended 66976
412.29 Introductory text amended 66976
412.30 (c) and (d)(2)(ii) revised 25776

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412.63 Heading, (a), (c)(1), (5), (6) and (u) revised; (b) introductory text added 49241
412.64 Added 49242
412.87 (b)(3) revised 49243
412.88 (c) removed 49244
412.101 Added 49244
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412.103 (a) introductory text revised; (a)(4) added 49244
(a)(4) corrected 60252
412.104 (a) revised 49244
412.105 (e) and (f)(1)(iv) redesignated as (e)(1) and (f)(1)(iv)(A); (b) and (d)(3)(vii) revised; (d)(3)(viii) through (xii), (4), (e)(2), (f)(1)(iv)(B) and (C) added; (a)(1) introductory text, (f)(1)(i)(A), (ii)(C), (vi) through (xii) and (g) amended 49244
412.106 (a)(1)(ii)(B), (C), (b)(2)(i) introductory text, (d)(2)(ii), (iii) and (iv) revised; (a)(1)(ii)(D) added; (a)(1)(iii) amended 49246
412.108 (a)(1) introductory text revised 49247
412.116 (a)(3) and (4) redesignated as (a)(4) and (5); new (a)(3) added 66977
412.130 (a)(1) and (2) amended 66977
412.204 (a) introductory text and (b) introductory text revised; (c) and (d) added 49247
412.210 Heading and (a)(1) revised 49247
412.211 Added 49248
412.212 (b) revised 49248
412.230 (a)(5)(ii), (d) and (e)(2)(i)(C) removed; (a)(5)(iii), (iv), (v) and (e) redesignated as (a)(5)(ii), (iii), (iv) and (d); (a)(1), (4), new (d)(3)(i) and (ii) revised; new (d)(1), (2)(iii), (4) introductory text and (iii) amended; (d)(3)(iii)(C) added 49249
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(d)(1)(iii)(A), (B) and (3) revised; (d)(1)(iii)(C) added 78529
412.232 (a)(1), (4) and (b) revised 49249
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412.234 (c) removed; (d) redesignated as (c); (a)(3), (4) and new (c) revised 49249
412.236 Removed 49250
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412.274 (b)(1) revised 49250
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412.320 (a)(1) revised 49250
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412.521 (e) added 49250
412.525 (d)(2) revised 25721
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412.532 (f) and (i) amended 25722
412.534 Added 49251
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413 Authority citation revised 49252, 66981
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413.1 (d)(2)(ii) revised; (d)(2)(iv) through (vii) redesignated as (d)(2)(vi) through (ix); new (d)(2)(iv) and (v) added 66981
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413.64 (h)(2) introductory text revised; (h)(2)(vi) added; (h)(3)(iv) and (4) removed 49252
(h)(2)(i) revised 66981
413.70 (a) heading, (1), (b)(2)(i), (iii), (3) heading, (i), (ii) and (4) revised; (a)(4), (d) and (e) added 49252
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413.77 (f) corrected 60252
413.79 (a)(10) corrected 60252
(a)(10) revised 78530
413.80 Redesignated as 413.89 49254
413.85 (b)(2) and (c)(3) amended 49254

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413.86 Removed 49254
413.75—413.83 (Subpart F) Added 49254
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413.88 (b)(1), (2), (d)(7), (g)(1)(i)(A), (B) and (h)(1)(i) amended 49265
413.114 (a)(2) amended 49265
413.302 Amended 49265
414 Technical correction 15703, 15729, 35527
414.1 Amended; interim 1116
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414.65 (a)(1) revised 66424
414.66 Added 66424
414.67 Added 66424
414.610 (c)(1) and (5) revised; (c)(7) added; interim 40292
414.617 Added; interim 40292
414.701—414.707 (Subpart I) Added; interim 1116
414.800—414.806 (Subpart J) Added; interim 17938
414.804 (a)(3) revised 55765
414.900—414.904 (Subpart K) Added 66424
414.1000—414.1001 (Subpart L) Added 66425
418 Application deadline 69536
418.100 (d)(1) and (4) revised; (d)(5) added 49266
418.205 Added 66425
418.304 (d) added 66426
419 Technical correction 78315
419.21 (e) added 65863
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419.32 (d) revised; interim 832
419.43 (d)(1) introductory text and (e) revised; (f) added; interim 832
419.64 (d) revised 65863
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424.80 (a), (b)(2) and (c) revised; (b)(3) removed; (b)(4), (5) and (6) redesignated as (b)(3), (4) and 5; (d) added 66426

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401.108 (c) revised; interim 11472
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403.205 Revised 4525
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403.766 (a) introductory text revised 16721
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403.813 (a)(1) revised 52023
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405.990 (b)(1)(i)(A) correctly revised; interim 37703
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405.1014 (c)(4) corrected 37703
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405.1028 Heading corrected 37704
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412.64 (b)(5) added; (i)(3)(iv) and (k)(2) revised 47485
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412.278 (b)(1) amended 47487
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417.606 Removed; eff. 1–1–06 4713
417.608 Removed; eff. 1–1–06 4713
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417.616 Removed; eff. 1–1–06 4713
417.617 Removed; eff. 1–1–06 4713
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417.622 Removed; eff. 1–1–06 4713
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422.56 Heading, (a) and (b) revised 4716
422.60 (b)(1), (3), (c) heading, (1), (d), (e), (f)(1) and (3) revised 4716
(f) introductory text corrected 52026
422.62 Heading, (a), (b) introductory text, (d) heading and (1) revised; (d)(2)(i)(A) removed; (d)(2)(i)(B) and (C) redesignated as (d)(2)(i)(A) and (B) 4717
422.66 Heading, (b)(1)(i), (ii), (3)(ii), (iii) introductory text, (d)(5), (e) and (f)(2) revised 4718
(f)(1) corrected 52026
422.68 (b) revised 4718
422.74 Heading, (b)(1)(ii), (c)(1), (d)(1) and (2) revised; (b)(2)(iv) added 4718
422.80 (a) and (e)(1)(ii) through (v) revised; (e)(1)(ix) added 4719
422.100 (e) removed; (f) through (j) redesignated as (e) through (i); (b)(2), (c)(1), new (f) introductory text and (2) revised 4719
(d)(2) amended 52026
422.101 (b)(2) and (3) introductory text revised; (b)(4), (5), (d) and (e) added 4720
Introductory text, (b)(3)(i) and (d)(1) corrected 52026
422.102 (a)(1) and (3) revised; (a)(4) added 4720
422.103 Heading and (a) revised 4720
(d)(2) corrected 52026
422.105 Heading, (a) and (b) revised 4720
422.106 (c) heading and (2); (d) added 4721
422.108 (f) revised 4721
422.109 (a)(2), (c)(2)(iv) and (3) revised 4721
(a)(1)(ii) corrected 52026
422.110 (b) revised; (c) removed 4721
422.111 (b)(3) introductory text, (f)(5) and (7) through (11) redesignated as (b)(3)(i) and (f)(4) through (9); (b)(2) introductory text, (9), (c)(1), (d)(2), (e), new (f)(5)(iv) and (9) revised; (b)(3)(ii), (11), (f)(10), (11) and (12) added; (f)(4), new (5)(v) and (6) removed; new (f)(5)(vi), (vii) and (viii) redesignated as new (f)(5)(v), (vi) and (vii) 4721
(b)(2) corrected 52026

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422.112 (a) heading, introductory text, (1), (b) heading and introductory text revised; (a)(4) removed; (a)(5) through (10) redesignated as (a)(4) through (9); (c) added 4722
422.113 (b)(2)(v) and (c)(2)(iv) revised 4723
422.114 Heading revised; (c) added 4723
422.132 Amended 52026
422.133 (b)(4) added 4723
422.152—422.158 (Subpart D) Nomenclature change 4723
422.152 Revised 4723
(a)(1) and (c) stayed to 1–1–06; (b)(3)(ii) corrected 52026
422.154 Removed 4724
422.156 (b)(1) revised; (b)(7) added 4724
(b)(7) stayed to 1–1–06 52026
422.202 (b) introductory text amended 4724
422.204 (b)(2)(ii) amended 4724
422.206 (b)(2)(i) amended 52026
422.208 (c)(2) revised; (h) removed; (i) redesignated as (h) 4724
(c)(2) corrected 52026
422.210 Revised 4724, 52026
422.214 (a)(1) and (b) revised 4724
(b) amended 47490
422.216 (a)(4) amended 47490
(b)(2) amended 52026
422.250—422.270 (Subpart F) Revised 4725
422.252 Corrected 52026
422.254 (b)(1)(i) corrected 52026
422.256 (c) corrected 52027
422.300—422.324 (Subpart G) Revised 4729
422.314 (c)(1)(i) corrected 52027
422.316 Stayed to 1–1–06 52027
422.320 (c)(1) and (2)(ii) corrected 52027
422.322 (b) and (c) corrected 52027
422.402 Revised 4733
422.404 (a) revised 4733
422.451—422.458 (Subpart J) Added 4733
422.458 (d)(2) revised 52027
422.500 Heading revised; existing text designated as (b) and amended; (a) added 4736
(b)(1) corrected 52027
422.501 Redesignated as 422.503; new 422.501 added 4736

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422.502 Redesignated as 422.504; new 422.502 added 4736
422.503 Redesignated from 422.501; (b)(1) through (5) redesignated as (b)(2) through (6); new (b)(1) added; new (b)(4)(ii), (vi)(F), (6) introductory text and (i) revised; (b)(4)(vi)(G)(*1*), (*2*) and (H) added 4737
(b)(4)(vi)(H) and (d)(1) corrected 52027
422.504 Redesignated as 422.505; new 422.504 redesignated from 422.502 4736
(e)(4) introductory text, (ii), (iii), (h) and (i)(3)(ii) revised; (f)(2)(vii) removed; (f)(2)(viii) redesignated as (f)(2)(vii) 4737
(a)(8), (9), (10), (d) introductory text, (1)(i), (iv), (v), (2)(ii), (iii), (e)(1)(iii), (h)(1), (i)(2)(ii), (l) introductory text, (2), (3) and (4) corrected 52027
422.505 Redesignated from 422.504 4736
(d) added 4737
422.506 (a)(2)(i), (ii) and (3) introductory text revised 4737
422.510 (a)(4) revised 4738
(a)(4) and (7) corrected 52027
422.520 Heading and (a)(3) revised; (b) introductory text redesignated as (b)(1); (b)(2) and (d) added 4738
422.527 Added 4738
Stayed 9–1–05 to 1–1–06 52027
422.550 (a)(2) revised 4738
422.552 (a) and (3)(iii) amended 52027
422.553 (b)(2) amended 52027
422.560 (a)(3) and (c) added 4738

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422.561 Amended 4738
422.562 (b)(4)(iv), (vi), (c)(1)(ii) and (d) revised 4738
(c)(1)(ii) corrected 52027
422.564 (d) and (e) redesignated as (f) and (g); new (d) and (e) added 4738
422.566 (b)(4) revised 4739
422.568 (a) and (c) revised 4739
(d) revised 52027
422.570 (d)(2)(ii) revised 4739
422.572 (b) and (c) revised 4739
422.582 (a), (b) and (c)(2) introductory text revised 4739
422.584 (e) revised 4739
422.590 (a)(1) and (d)(2) revised 4739
422.600 (a) and (b) revised 4740
422.602 (a), (b) and (d) revised 4740
422.608 Revised 4740
422.612 (a)(2), (b) and (c) revised 4740
422.616 (a) revised 4740
422.620 Heading, (b) and (c) revised 4740
422.622 (b)(1)(i) revised 4740
(b)(1)(i) revised 52027
422.648 (c) added 4741
422.752 (a) introductory text, (8) introductory text and (b) revised 4741
(a)(2) corrected 52027
422.756 (f)(2) and (3) revised 4741
422.758 Introductory text and (c) revised 4741
423 Added 4525
Policy statement 13397
424 Technical corrections 57165
424.3 Amended 45055
424.20 (e)(2) revised 45055
424.80 (a) revised 16722