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Public Health

42

PARTS 400 TO 429

Revised as of October 1, 1996

CONTAINING
A CODIFICATION OF DOCUMENTS
OF GENERAL APPLICABILITY
AND FUTURE EFFECT

AS OF OCTOBER 1, 1996

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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 contents of the Federal Register are required to be judicially noticed (44 U.S.C. 1507). The Code of Federal Regulations is prima facie evidence of the text of the original documents (44 U.S.C. 1510).

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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.

Many agencies have begun publishing numerous OMB control numbers as amendments to existing regulations in the CFR. These OMB numbers are placed as close as possible to the applicable recordkeeping or reporting requirements.

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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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(a) The incorporation will substantially reduce the volume of material published in the Federal Register.

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

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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), and Acts Requiring Publication in the Federal Register (Table II). 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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RICHARD L. CLAYPOOLE,
Director,
Office of the Federal Register.

October 1, 1996.

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—Health Care Financing Administration (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, 1996.

The OMB control numbers for the Health Care Financing Administration 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.

Redesignation tables appear in the Finding Aids section of all volumes.

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

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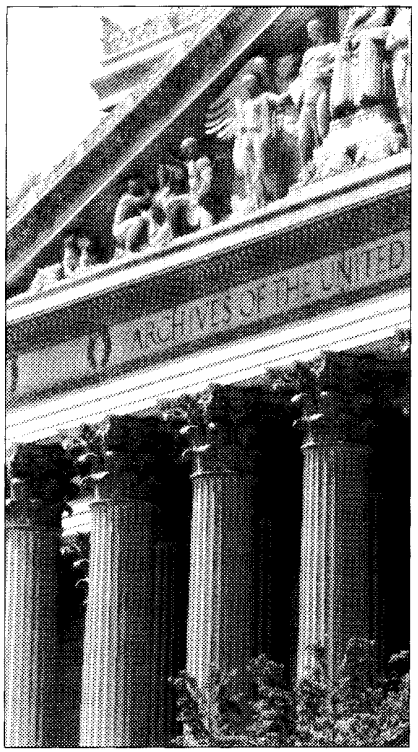

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Title 42—Public Health

(This volume contains parts 400 to 429)

Part

CHAPTER IV—Health Care Financing Administration, Department of Health and Human Services 400

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

EDITORIAL NOTE: Nomenclature changes affecting chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991.

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SUBCHAPTER A—GENERAL PROVISIONS

PART 400—INTRODUCTION; DEFINITIONS

Subpart A—[Reserved]

Subpart B—Definitions

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400.200 General definitions.
400.202 Definitions specific to Medicare.
400.203 Definitions specific to Medicaid.

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, Health Care Financing Administration.

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.

CY stands for calendar year.

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.

HCFA stands for Health Care Financing Administration.

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.

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.

PRO stands for Utilization and Quality Control Peer Review Organization.

QDWI stands for Qualified Disabled and Working Individual.

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.

Regional Administrator means a Regional Administrator of HCFA.

Regional Office means one of the regional offices of HCFA.

RHC stands for rural health clinic.

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.

Utilization and Quality Control Peer Review Organization (PRO) means an organization that has a contract with HCFA to review, under Part B of title XI of the Act, the health care services or items furnished or proposed to be furnished to Medicare beneficiaries.

[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]

§ 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 HCFA to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

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

Essential access community hospital (EACH) means a hospital designated by HCFA as meeting the applicable requirements of section 1820 of the Act and of subpart G of part 412 of this chapter.

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 HCFA to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

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.

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, an RPCH, 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).

Rural primary care hospital (RPCH) means a facility designated by HCFA as meeting the applicable requirements of section 1820 of the Act and of subpart F of part 485 of this chapter.

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, RPCH, 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]

§ 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.

Provider means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency.

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]

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 HCFA regulations, in accordance with OMB's regulations for controlling paperwork burdens on the public, 5 CFR part 1320. HCFA 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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Subpart F—Claims Collection and Compromise

401.601 Basis and scope.
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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1895hh). 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 Health Care Financing Administration (HCFA). The rules apply to information obtained by officers or employees of HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA as having precedent, may be published in the FEDERAL REGISTER as a HCFA Ruling and will be made available in the publication entitled *HCFA Rulings.*

(b) Precedent final opinions and orders and statements of policy and interpretation that were adopted by HCFA before October, 1981, and that have not been published in the FEDERAL REGISTER are available in *HCFA Rulings.*

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

[48 FR 22924, May 23, 1983]

§ 401.110 Publications for sale.

The following publications containing information pertaining to the program, organization, functions, and procedures of HCFA 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) HCFA 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 HCFA 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 HCFA 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, HCFA 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 HCFA 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, HCFA 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) HCFA may release the accreditation survey of any home health agency; and

(B) HCFA 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 HCFA; 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 HCFA component;

(2) Director, Office of Public Affairs, HCFA 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, Altanta, 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.* HCFA 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, HCFA, Baltimore, Maryland 21235, when information is sought from the record of a person who has participated in a research survey conducted by or for HCFA, 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 HCFA Rulings.* A request to inspect and copy materials listed in § 401.130 or § 401.132 or indexed in HCFA 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 Health Care Financing Administration. 42 CFR chapter IV .

(4) HCFA 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, HCFA.

(3) Parts 2 and 3 of the Part A Intermediary Manual (Provider Services under Medicare HCFA 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) HCFA Letters to State Agencies on Medicare.

(10) Skilled Nursing Facility Manual (HCFA 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 HCFA.

(3) Title 5, United States Code.

(4) Compilation of the Social Security Laws.

(5) HCFA 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 HCFA, 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 HCFA. (See § 401.130(b)(17)) for places where statements of deficiencies, reports, and pertinent written statements will be available.)

(b) *HCFA 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 HCFA 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 HCFA 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 HCFA (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 HCFA by those intermediaries, carriers, on State agencies or those reports and evaluations.

(d) *Accreditation surveys.* Upon written request, HCFA 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 HCFA;

(e) Upon written request, HCFA 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 HCFA 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 HCFA 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 HCFA 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, HCFA and to the Director of Public Affairs in any HHS Regional Office. Those officers and employees of HCFA 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 HCFA'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, HCFA, and the Regional Directors of Public Affairs, HHS, are authorized to deny written requests to obtain, inspect or copy any HCFA 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 HCFA, 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 HCFA 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 HCFA'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 HCFA by the Secretary.

(c) *Amount of claim.* HCFA 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 HCFA that generally implement the FCCA for the Department are located at 45 CFR part 30.

(2) *HCFA regulations.* The following regulations govern specific debt management situations encountered by HCFA 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 §§ 405.374 and 405.376 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 HCFA 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 HCFA 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. HCFA forwards these claims to the Department of Justice for disposition under 4 CFR 105.1.

(g) *Enforced collection.* HCFA 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]

EFFECTIVE DATE NOTE: At 61 FR 49271, Sept. 19, 1996, § 401.601 was amended by revising paragraph (d)(2)(ii), effective Oct. 21, 1996. For the convenience of the user the superseded text is set forth as follows:

§ 401.601 Basis and scope.

* * * * *

(d) * * *

(2) * * *

(ii) Adjustments in Railroad Retirement or Social Security benefits to recover Medicare overpayments to individuals are covered in §§ 405.350—405.356 of this chapter.

* * * * *

§ 401.603 Definitions.

For purposes of this subpart—

Claim means any debt owed to HCFA.

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

§ 401.605 Omissions not a defense.

The failure of HCFA 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 HCFA has a claim for money or property.

§ 401.607 Claims collection.

(a) *General policy.* HCFA 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, HCFA attempts to collect claims in full in one lump sum. However, if HCFA determines that a debtor is unable to pay the claim in one lump sum, HCFA may instead enter into an agreement to accept regular installment payments.

(c) *Collection in installments.* Generally, HCFA 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 HCFA; and

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

(2) *HCFA decision.* HCFA 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 HCFA of administering an installment agreement.

(d) *Collection by offset.* (1) In conformity with 4 CFR 102.3, HCFA 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, HCFA 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]

EFFECTIVE DATE NOTE: At 61 FR 49271, Sept. 19, 1996, § 401.607 was amended by revising paragraph (d)(2), effective Oct. 21, 1996. For the convenience of the user the superseded text is set forth as follows:

§ 401.607 Claims collection.

* * * * *

(d) * * *

(2) Under regulations at §§ 405.350—405.356 of this chapter, HCFA 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.

§ 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, HCFA 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 HCFA may compromise a claim include the following—

(1) *Inability to pay.* HCFA 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.* HCFA 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 HCFA accepts in compromise under this provision will reflect—

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

(ii) Whether and to what extent HCFA would have obtained a full or partial recovery of a judgment, depending on the availability of witnesses, or

other evidentiary support for HCFA's claim; and

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

(3) *Cost of collecting the claim.* HCFA 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, HCFA 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.* HCFA 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 HCFA 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 HCFA. Accordingly, HCFA 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.* HCFA 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.* HCFA may temporarily suspend collection action on a claim if the following general conditions are met—

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

(2) *Statute of limitations.* HCFA 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 HCFA through offset despite an applicable statute of limitations.

(b) *Basis for suspension.* Bases on which HCFA 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 HCFA's claim or is unable to effect a compromise; and

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

(c) *Locating debtors.* HCFA 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.* HCFA 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, HCFA 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 HCFA may terminate collection action on a claim include the following—

(1) *Inability to collect a substantial amount of the claim.* HCFA 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, HCFA 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, HCFA 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 HCFA to be too remote to justify retention of the claim.

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

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

(5) *Evidence unavailable.* HCFA 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.* HCFA will liquidate claims as quickly as possible. In cases of joint and several liability among two or more debtors, HCFA will not allocate the burden of claims payment among the debtors. HCFA 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, HCFA 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 HCFA 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 HCFA appeal procedures.

PART 402—[RESERVED]

PART 403—SPECIAL PROGRAMS AND PROJECTS

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AUTHORITY: 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 HCFA 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 (d) of this section, *Medicare supplemental policy* (policy) means a health insurance policy or other health benefit plan—

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

(2) That 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) Unless otherwise specified in this subpart, the term *policy* includes both policy form and policy.

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

(2) *Policy* means the contract—

(i) Issued under the policy form; and

(ii) Held by the policyholder.

(c) Medicare supplemental policy includes the following—

(1) An individual policy.

(2) A group policy.

(d) Medicare supplemental policy does not include any of the following health insurance policies or health benefit plans—

(1) A policy or plan of one or more employers for employees, former employees, or any combination thereof.

(2) A policy or plan of one or more labor organizations for members, former members, or any combination thereof.

(3) A policy or plan of the trustees of a fund established by one or more labor organizations, one or more employers, or any combination, for any one or combination of the following—

(i) Employees.

(ii) Former employees.

(iii) Members.

(iv) Former members.

(4) A policy or plan of a profession, trade, or occupational association, if the association—

(i) Is composed of individuals all of whom are actively engaged in the same profession, trade, or occupation;

(ii) Has been maintained in good faith for a purpose other than obtaining insurance; and

(iii) Has been in existence for at least two years before the date of its initial offering of a Medicare supplemental health insurance policy to its members.

(5) For purposes of the voluntary certification program, a policy issued to an employee or to a member of a labor organization as an addition to a franchise plan (a plan that enables members of the same entity to purchase an individual policy marketed to them under group underwriting procedures), if the plan is in existence on July 1, 1982.

§ 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 HCFA 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 HCFA 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 HCFA 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 HCFA, 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 HCFA 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 HCFA/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 HCFA for review is accurate and complete and does not misrepresent any material fact.

§ 403.235 Review and certification of policies.

(a) HCFA will review policies that the insuring organization voluntarily submits, except that HCFA 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, HCFA 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 HCFA 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) HCFA certification of a policy that continues to meet the standards will remain in effect, if the insuring organization files the following material with HCFA 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 HCFA 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 HCFA 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 HCFA—

(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 HCFA, ends before the June 30 date of paragraph (b) of this section, the insuring organization must file the material with HCFA 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) HCFA 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, HCFA 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 HCFA determinations.

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

(1) Not to certify a policy; or

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

(b) If HCFA 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 HCFA 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 HCFA determination; and

(ii) Submit additional information to HCFA for review.

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

(5) That, in a case involving loss of certification, the HCFA 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 HCFA makes a final determination.

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

(1) A HCFA official, not involved in the initial HCFA 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 HCFA for review, as specified in § 403.232(b) or § 403.239(a); and

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

(3) Within 15 days after the administrative review is completed, HCFA 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 HCFA'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 HCFA 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 HCFA.

(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 HCFA certification under § 403.232, the insuring organization must submit the following loss ratio data to HCFA 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 HCFA certification under § 403.239(a), the insuring organization must submit the following to HCFA—

(1) A description of all changes in the loss ratio data, specified in paragraph (a) of this section, that occurred since HCFA 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 HCFA 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 HCFA'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 HCFA;

(2) A description of HCFA'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 HCFA 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 HCFA 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 HCFA.* HCFA may approve Medicare payments under a State system, if HCFA 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 HCFA 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 Peer Review 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 HCFA 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 HCFA, to review and monitor the State's assurances; and

(ii) Submission of the reports to HCFA 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 HCFA 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 HCFA 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 HCFA 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.* HCFA 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 HCFA and to the hospitals likely to be materially affected by the change and upon HCFA'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.

HCFA 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 HCFA 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, HCFA 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 § 405.376 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 HCFA'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.

§ 403.312 Submittal of application.

The Chief Executive Officer of the State is responsible for—

(a) Submittal of the application to HCFA for approval; and

(b) Supplying the assurances and necessary documentation as required under §§ 403.304 through 403.308.

§ 403.314 Evaluation of State systems.

HCFA 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 HCFA denies an application for a State system, the State may request that HCFA 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 HCFA's notice that the application was denied.

(2) HCFA 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 HCFA approves a State system, a written agreement will be executed between HCFA 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 HCFA's approval of the State's reporting forms

and of provider cost reporting forms or other forms that have not been approved by HCFA 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 HCFA 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 HCFA 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. HCFA 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. HCFA 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.* HCFA will review the State's assurances and data submitted under this section, as a prerequisite to the approval of the State's system. HCFA will compare the State's projections of payment amounts to HCFA data in order to determine if the State's assurance is reasonable and fully supportable. If the HCFA 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 HCFA 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.* HCFA 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 HCFA 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). HCFA 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.

HCFA 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) HCFA 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) HCFA 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) HCFA will give the State the opportunity to present evidence to refute the finding.

(4) HCFA 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 HCFA notice of its intent to terminate. A termination must be effective on the last day of a calendar quarter. The State must notify HCFA

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 HCFA 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 HCFA.

§ 403.502 Availability of grants.

HCFA awards funds to States subject to congressional appropriations 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 is specified in the notice of grant award sent to each State. HCFA advises each State as to when to make application and provides information as to the timing of the grant award and the duration of the grant award. HCFA also provides an estimate of the amount of funds that may be available to the State.

§ 403.504 Number and size of grants.

(a) *General.* HCFA awards the following types of grants:

(1) New program grants.

(2) Existing program enhancement grants.

(b) *Grant Award.* Each eligible State that submits an acceptable application receives a grant including 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) HCFA 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 HCFA 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), HCFA 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 HCFA, along with its acceptance of the grant award, that reflects the amount awarded.

§ 403.508 Limitations.

(a) *Use of grants.* Except as specified in paragraph (b) of this section, a State that receives a grant under this subpart may use the grant for any reasonable expenses incurred in planning, developing, implementing, and/or operating the program for which the grant is made.

(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.

§ 403.510 Reporting requirements.

A State that receives a grant under this subpart must submit at least one annual report to HCFA and any additional reports as HCFA may prescribe in the notice of grant award. HCFA 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.* HCFA provides notice to each applicant regarding HCFA'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 HCFA's determination regarding its application. Appeal procedures are governed by the regulations at 45 CFR part 16 (Procedures of the Departmental Grant Appeals Board).

SUBCHAPTER B—MEDICARE PROGRAM

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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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) HCFA uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) HCFA 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 HCFA 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 HCFA, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).

(c) HCFA 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 HCFA, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).

(2) HCFA 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 HCFA 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 HCFA 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 services, ordinarily covered by Medicare, to treat a condition or complication that arises because of the use of a noncovered device or from the furnishing of related noncovered services.

§ 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 HCFA 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 HCFA 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 HCFA'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 HCFA and the sponsor of its decision.

(c) *Request to HCFA.* If the FDA does not agree to recategorize the device, the sponsor may seek review from HCFA. A device sponsor must submit its request in writing to HCFA. HCFA obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. HCFA reviews all material submitted by the sponsor and the FDA's recommendation. HCFA reviews only information in the FDA record to determine whether to change the categorization of the device. HCFA 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 HCFA relies on confidential commercial or trade secret information in any judicial proceeding, HCFA 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 Health Care Financing Administration 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]

EFFECTIVE DATE NOTE: At 61 FR 49271, Sept. 19, 1996, § 405.350 was amended by revising the introductory paragraph, effective Oct. 21, 1996. For the convenience of the user the superseded text is set forth as follows:

§ 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 405.356, where:

* * * * *

§ 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]

EFFECTIVE DATE NOTE: At 61 FR 49271, Sept. 19, 1996, § 405.356 was revised, effective Oct. 21, 1996. For the convenience of the user the superseded text is set forth as follows:

§ 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 20 CFR 404.506–404.509, 404.510a, and 404.512.

[35 FR 6321, Apr. 18, 1970. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 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]

EFFECTIVE DATE NOTE: At 61 FR 49271, Sept. 19, 1996, § 405.357 was added, effective Oct. 21, 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]

EFFECTIVE DATE NOTE: At 61 FR 49271, Sept. 19, 1996, § 405.358 was added, effective Oct. 21, 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 OF PAYMENT TO PROVIDERS AND SUPPLIERS AND COLLECTION AND COMPROMISE OF OVERPAYMENTS

§ 405.370 Suspension of Medicare payments to providers and suppliers.

(a) Medicare payments to providers and suppliers, as authorized under this chapter (excluding payments to beneficiaries), may be suspended, in whole or in part, by an intermediary or a carrier when—

(1) The intermediary or carrier has determined that the provider or other supplier to whom such payments are to be made has been overpaid under title XVIII of the Social Security Act, or

(2) The intermediary or carrier has reliable evidence, although additional

evidence may be needed for a determination, that such overpayment exists or that the payments to be made may not be correct.

(b) A suspension shall be put into effect only after the provisions in §§ 405.371 and 405.372 have been complied with and the intermediary or carrier has determined that the suspension of payments, in whole or in part, is needed to protect the program against financial loss. The provisions of this section and §§ 405.371–405.373 shall be effective on May 27, 1972.

[37 FR 10723, May 27, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6647, Mar. 2, 1988]

§ 405.371 Proceeding for suspension.

(a) *General.* Whenever the intermediary or carrier has determined that a suspension of payments under § 405.370 should be put into effect with respect to a provider of services or other supplier of services, the intermediary or carrier shall notify the provider or other supplier of its intention to suspend payments, in whole or in part, and the reasons for making such suspension. The provider or other supplier will be given the opportunity to submit any statement (including any pertinent evidence) as to why the suspension shall not be put into effect and shall have 15 days following the date of notification to submit such statement, unless the intermediary or carrier for good cause imposes a shorter period. The intermediary or carrier may, for good cause shown, extend the time within which the statement may be submitted. If no statement is received within the 15-day period or such other period as specified in the notice, the suspension shall go into effect.

(b) *Fraud or misrepresentation.* The provisions of paragraph (a) of this section shall not apply where the intermediary or carrier has reliable evidence that the circumstances giving rise to the need for a suspension of payments involves fraud or willful misrepresentation. Instead, the intermediary or carrier may suspend payments without first notifying the provider or other supplier of an intention to suspend payments. The provider or other supplier will be notified of such suspension and the reasons for taking such action.

(c) *Notice of amount of program reimbursement.* The provisions of paragraph (a) of this section shall not apply where the intermediary, after furnishing a provider a written notice of the amount of program reimbursement pursuant to § 405.1803, suspends payment under paragraph (b) of such § 405.1803.

(d) *Failure to furnish information requested.* The provisions of paragraph (a) of this section shall not apply where the intermediary or carrier suspends payments to a provider or other supplier of services because such provider or supplier of services has failed to submit evidence requested by such intermediary or carrier which is needed to determine the amounts due such provider or supplier under the program (sections 1815 and 1833(e) of the Act).

[37 FR 10723, May 27, 1972, as amended at 41 FR 52050, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.372 Submission of evidence and notification of administrative determination to suspend.

When pursuant to § 405.371(a) the provider or other supplier submits a statement, the intermediary or carrier shall consider such statement (including any pertinent evidence submitted), together with any other material bearing upon the case, and make a determination as to whether the facts justify a suspension authorized by § 405.373. If the intermediary or carrier determines that a suspension should go into effect, written notice of such determination will be sent to the provider or other supplier. Such notice will contain specific findings on the conditions upon which the suspension was based, and an explanatory statement for the final decision.

[37 FR 10723, May 27, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.373 Subsequent action by intermediary or carrier.

(a) Where a suspension is put into effect by reason of § 405.370(a)(1), such suspension shall remain in effect until whichever of the following first occurs:

(1) The overpayment is liquidated, (2) the intermediary or carrier enters into

an agreement with the provider or other supplier for liquidation of the overpayment, or (3) the intermediary or carrier, on the basis of subsequently acquired evidence or otherwise, determines that there is no overpayment; except that the intermediary or carrier may at any time adjust such suspension for an appropriate period if it determines that continuation of the suspension would cause irreparable harm to the provider or other supplier.

(b) Where the suspension is put into effect by reason of § 405.370(a)(2), the intermediary or carrier will take timely action after such suspension to obtain such additional evidence it may need to make a determination as to whether an overpayment exists or the payments may be made (i.e., evidence from the records of the provider or other supplier of services). All reasonable efforts will be made by the intermediary or carrier to expedite such determinations. As soon as such determination is made, the provider or other supplier will be informed and, where appropriate such suspension will be rescinded or adjusted to take into account such determination. If such suspension is not rescinded, it shall remain in effect as specified in paragraph (a) of this section.

(c) The provisions of this section shall not apply where the intermediary or carrier, in suspending payments pursuant to § 405.370, has reliable evidence that the circumstances giving rise to such suspension involve fraud or serious misrepresentation.

[37 FR 10723, May 27, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.374 Collection and compromise of claims for overpayments.

(a) *Scope.* This section contains requirements and procedures for the compromise of, or suspension or termination of collection action on, claims for overpayments against a provider, physician, or other supplier of services under the Medicare program. It is adopted pursuant to the Federal Claims Collection Act (31 U.S.C. 951–953). Collection and compromise of claims against Medicare beneficiaries is 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 Health Care Financing Administration (HCFA) 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.* 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.* 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, HCFA 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 HCFA 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 HCFA. 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 HCFA.

(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 HCFA 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]

§ 405.375 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 specified in paragraph (b) of this section that have not arranged to repay Medicaid overpayments as determined by the Medicaid agency or have failed to provide information necessary to determine the amount of overpayment.

(b) *When withholding may be used.* HCFA may withhold Medicare payments to recover 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 paragraphs (c)(1) or (c)(2) of this section.

(c) *Institutions or persons affected*— (1) HCFA may withhold Medicare payments to recover Medicaid overpayments 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:

(i) An institutional provider that has in effect an agreement under section 1866 of the Act.

(ii) A physician or supplier who has accepted payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act.

(2) HCFA may withhold Medicare payment from an institution or person specified in paragraph (c)(1) of this section that—

(i) Has not made arrangements satisfactory to the Medicaid agency to repay; or

(ii) Has not provided information to the Medicaid agency necessary to enable the agency to determine the existence or amount of Medicaid overpayment.

(d) *Amount to be withheld*—(1) HCFA will contact the appropriate intermediary or carrier to determine the amount of Medicare payment to which the institution or person is entitled.

(2) HCFA 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 HCFA intends to withhold payments under this section, HCFA will notify by certified mail, return receipt requested, the institution or person and the intermediary or carrier responsible for making Medicare payment to the institution or person of the intention to withhold Medicare payments. The notice will include:

(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.* HCFA will terminate the withholding if—

(1) The Medicaid overpayment is completely recovered;

(2) The institution or person makes 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.* HCFA will return to the Medicaid agency amounts withheld under this section to offset the agency's Medicaid overpayment.

[50 FR 19688, May 10, 1985]

§ 405.376 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) HCFA 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 will accrue from the date of the final determination as defined in paragraph (c) of this section, and will either be charged on the overpayment balance or paid on the underpayment balance for each 30-day period that payment is delayed. (Periods of less than 30 days will be treated as a full 30-day period, and the 30-day interest charge will be applied to any balance.)

(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 HCFA 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 HCFA, 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 HCFA 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 HCFA, 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) HCFA 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]

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—[Reserved]

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 HCFA 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 HCFA 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 non-

teaching 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 HCFA 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 Health Care Financing Administration, 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 Health Care Financing Administration. 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 reasonable charges in special circumstances: General.* HCFA or a carrier may establish special reasonable charge limits for a category of service if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in grossly deficient or excessive charges. The limit on the reasonable charge is an upper limit to correct a grossly excessive charge or a lower limit to correct a grossly deficient charge. The limit is either a specific dollar amount, or is based on a special method to be used in determining the reasonable charge.

(1) *Determination of excessive or deficient charges.* HCFA or a carrier may make a determination that the standard rules for calculating reasonable charges set forth in this subpart result in grossly deficient or excessive charges. HCFA's determination may apply to the services of any supplier; however, a carrier's determination may apply only to nonphysician services. Examples of the circumstances which may result in grossly deficient or excessive charges include, but are not limited to the following:

(i) The marketplace is not competitive. This includes circumstances in which the marketplace for a service is not truly competitive because a limited number of physicians perform the service.

(ii) Medicare and Medicaid are the sole or primary sources of payment for a service.

(iii) The charges involve the use of new technology for which an extensive charge history does not exist.

(iv) The charges do not reflect changing technology, increased facility with that technology, or changes in acquisition, production or supplier costs.

(v) The prevailing charges for a service in a particular locality are significantly in excess of or below prevailing charges in other comparable localities, taking into account the relative costs of furnishing the services in the different localities.

(vi) Charges are grossly lower than or in excess of acquisition or production costs.

(vii) There have been increases in charges for a service that cannot be explained by inflation or technology.

(viii) The prevailing charges for a service are substantially higher or lower than the payments made for the service by other purchasers in the same locality.

(2) *Establishing a limit.* In establishing a limit, HCFA or a carrier considers the available information that is relevant to the category of service and establishes a reasonable charge that is realistic and equitable. The factors to be considered in establishing a specific dollar amount or special method may include the following:

(i) *Price markup.* This is the relationship between the retail and wholesale prices or manufacturer's costs of a category of service. If information on a particular category of service is not available, HCFA or a carrier may consider the markup on similar services and information on general industry pricing trends.

(ii) *Differences in charges.* HCFA or a carrier may consider the differences in charges to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii) *Costs.* HCFA or a carrier may consider resources (overhead, time, acquisition costs, production costs, complexity, etc.) required to produce a service or a product.

(iv) *Utilization.* HCFA or a carrier may impute a reasonable rate of use for a category of service and consider unit costs based on efficient utilization.

(v) Charges in other localities.

(vi) Other relevant factors.

(3) *Notification of limits*—(i) *National limits.* When HCFA makes a determination regarding nonphysicians' services under this section, it publishes in the FEDERAL REGISTER proposed and final notices of a special reasonable charge limit before the limit is adopted. The notice sets forth in the FEDERAL REGISTER the criteria and circumstances, if any, under which a carrier may grant an exception to the limit.

(ii) *Carrier level limits.* After September 9, 1988, a carrier proposing to establish a generally applicable special reasonable charge limit must inform the affected suppliers and State Medicaid agencies of the factors considered in establishing the limit as described in paragraphs (g) (1) and (2) of this section and solicit comments. After evaluating the comments received, the carrier must inform the affected suppliers and State Medicaid agencies of any final limit established. The limit is effective for services furnished no fewer than 30 days after the date of the carrier's notification.

(h) *Determination of reasonable charges in special circumstances: Physician services.* In establishing special reasonable charge limits for a category of physician services, HCFA applies the general rules under paragraphs (g) (1) and (2) of this section and the following special rules:

(1) *Potential impact of special limit.* In determining whether to set a special reasonable charge limit for a category of physician service, HCFA considers the potential impact on quality, access, beneficiary liability, assignment rates, reasonable charge reductions on unassigned claims, and participation rates of physicians.

(2) *Physician consultation.* Before making a determination that a charge is not inherently reasonable by reason of its grossly excessive or deficient amount, HCFA consults with representatives of the physicians likely to be affected by any change in the reasonable charge.

(3) *Special limits based on comparison of charges in different localities.* HCFA

takes into account differences in practice costs before basing a special limit on the comparison of prevailing charges in different localities.

(4) *Factors considered in establishing a special limit.* (i) In establishing the specific dollar amount or special method under paragraph (g)(2) of this section, HCFA takes into account regional differences in fees unless there is substantial economic justification, as described in the proposed and final notices required under paragraphs (h)(5)(i) and (ii) of this section, for a uniform fee or a uniform payment limit.

(ii) In determining that a charge is not inherently reasonable by reason of its grossly excessive or deficient amount, and in establishing the specific dollar amount or special method under paragraphs (g) (1) and (2) of this section, HCFA may compare the charge to the—

(A) Resource costs (that is, factors such as the time required to provide a procedure, including pre-procedure evaluation and post-procedure follow-up; the complexity of the procedure; the training required to perform the procedure; and the risk involved in the procedure) for related services;

(B) Resource costs for the service over a period of time;

(C) Charges for the service in different geographic areas after accounting for differences in practice costs;

(D) Payments for a service allowed under Medicare Part B and by other payors; and

(E) Other relevant factors.

(5) *Publication of national limits.* When HCFA makes a determination under this section, it publishes in the FEDERAL REGISTER proposed and final notices of a special reasonable charge limit before the limit is adopted. The notice sets forth in the FEDERAL REGISTER the criteria and circumstances, if any, under which a carrier may grant an exception to the limit.

(i) *Proposed notice.* The proposed notice—

(A) Specifies the proposed charge or methodology to be established with respect to a service;

(B) Explains the factors and data that HCFA took into account in determining the charge or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(C) Explains the potential impacts of a limit on physicians' services as described in paragraph (h)(1) of this section; and

(D) Allows no less than 60 days for public comment on the proposal.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that HCFA took into consideration, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments and any comments made by the Physician Payment Review Commission.

(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 in the Finding Aids section of this volume.

§ 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 HCFA; or

(ii) The prevailing charge that, on the basis of statistical data and methodology acceptable to HCFA, 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

HCFA, 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]
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	HCFA 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 HCFA, 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, HCFA 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, and 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 Health Care Financing Administration. When the pertinent information has been reported, the Health Care Financing Administration 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 HCFA 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 HCFA 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 Health Care Financing Administration with all pertinent data and information for approval before the revision is implemented. The Health Care Financing Administration 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 Health Care Financing Administration 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, and 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 that are not paid on a cost or prospective payment basis.

(a) *Applicability.* Payment for a drug 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 includes a drug furnished incident to a physician's service and a drug furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in §413.170(c) of this chapter.

(b) *Methodology.* Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spoilage.

(c) *Multiple-Source drugs.* For multiple-source drugs, payment is based on the lower of the estimated acquisition cost described in paragraph (b) of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

[56 FR 59621, Nov. 25, 1991]

§ 405.534 Limitation on payment for screening mammography services.

(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]

§ 405.535 Special rules for nonparticipating physicians and suppliers furnishing screening mammography services.

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)(3) of this chapter.

[59 FR 49833, Sept. 30, 1994]

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 PRO);

(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. 951–953). See 20 CFR 404.515 for overpayment claims

against an individual, § 405.374 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]

§ 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 HCFA 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.* HCFA 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 final and 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 final and 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]

§ 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 Social Security Administration or the Health Care Financing Administration 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 Health Care Financing Administration 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]

§ 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 Social Security Administration or the Health Care Financing Administration 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 Health Care Financing Administration may extend the time for filing the request for reconsideration.

§ 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 Social Security Administration or the Health Care Financing Administration 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 Health Care Financing Administration as of the date it is filed with the intermediary.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.715 Reconsidered determination.

(a) In reconsidering an initial determination, the Health Care Financing Administration shall review such initial determination, the evidence and findings upon which such determination was based, and any additional evidence submitted to the Social Security Administration or the Health Care Financing Administration or otherwise obtained by the intermediary or the Health Care Financing Administration; 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]

§ 405.716 Notice of reconsidered determination.

Written notice of the reconsidered determination shall be mailed by the Health Care Financing Administration 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]

§ 405.717 Effect of a reconsidered determination.

The reconsidered determination shall be final and binding upon all parties unless a request for a hearing is filed with the Social Security Administration or the Health Care Financing Administration within 60 days after the date of receipt of notice of the reconsidered determination by such parties, or unless the reconsidered determination is revised in accordance with the provisions of § 405.750, or unless the expedited appeals process is used in accordance with § 405.718a. 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.

[41 FR 47917, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718 Expedited appeals process; conditions for use of such process.

In cases in which a reconsideration determination has been made or a higher level of appeal has been reached, an expedited appeals process may be used in lieu of the hearing and Departmental Appeals Board review, if the following conditions are met:

(a) A reconsideration determination has been made by the Secretary; and

(b) The individual is a party referred to in § 405.718b; and

(c) The individual has filed a written request for the expedited appeals process; and

(d) The individual has alleged, and the Secretary agrees, that the only factor precluding a favorable determination with respect to a matter referred to in § 405.704, is a statutory provision which the individual alleges to be unconstitutional; and

(e) Where more than one individual is a party referred to in § 405.718b, each and every party concurs in the request for the expedited appeals process.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 32348, June 24, 1996]

§ 405.718a Expedited appeals process; place and time of filing request.

(a) *Place of filing request.* The request for the expedited appeals process must be made in writing and filed:

(1) At an office of the Social Security Administration or the Health Care Financing Administration; or

(2) In the case of an individual in the Philippines, at the Veterans Administration Regional Office in the Philippines or with a presiding officer; or

(3) In the case of a qualified railroad retirement beneficiary (see 20 CFR 404.368), at an office of the Railroad Retirement Board.

(b) *Time of filing request.* The request for the expedited appeals process must be filed at one of the following times:

(1) No later than 60 days after the date of receipt of notice of the reconsidered determination, unless the time is extended in accordance with the standards set out in 20 CFR 404.925(c). For purposes of this paragraph, 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; or

(2) If a request for hearing has been timely filed (see § 405.722), at any time prior to the individual's receipt of notice of the presiding officer's decision; or

(3) Within 60 days after the date of receipt of notice of the presiding officer'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 paragraph, the date of receipt of notice of the presiding officer's decision or dismissal shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary; or

(4) If a request for review by the Departmental Appeals Board has been timely filed (see 20 CFR 404.968) at any time prior to receipt by such individual

of notice of the Departmental Appeals Board's final action.

[40 FR 53387, Nov. 18, 1975, as amended at 41 FR 47917, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 45 FR 73933, Nov. 7, 1980; 61 FR 32348, June 24, 1996]

§ 405.718b Expedited appeals process; parties.

The parties to the expedited appeals process shall be the person or persons who were parties to the reconsideration determination in question and, if appropriate, parties to the hearing.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718c Expedited appeals process; agreement requirements.

(a)(1) An authorized representative of the Secretary shall, if he determines that all conditions for the use of the expedited appeals process are met (see § 405.718), prepare an agreement for signature of the party (parties) and an authorized representative of the Secretary.

(2)(i) Where a request for hearing has been filed, but prior to issuance of a decision a request for the expedited appeals process is filed, the Chief Administrative Law Judge of the Bureau of Hearings and Appeals, or his designee, shall determine if the conditions required for entering an agreement are met.

(ii) Where a hearing decision was the last action, or where a request for review is pending before the Departmental Appeals Board, and a request for the expedited appeals process is filed, the Chairman or Deputy Chairman of the Departmental Appeals Board or the Chairman's designee, shall determine if the conditions required for an agreement are met.

(b) An agreement with respect to the expedited appeals process shall provide that:

(1) The facts involved in the claim are not in dispute; and

(2) Except as indicated in paragraph (b)(3) of this section, the Secretary's interpretation of the law is not in dispute; and

(3) The sole issue(s) in dispute is the application of a statutory provision(s) which is described therein and which is alleged to be unconstitutional by the party requesting use of such process; and

(4) Except for the provision challenged, the right(s) of the party is established; and

(5) The determination or decision made by the Secretary is final for purposes of section 205(g) of the Act.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 32348, June 24, 1996]

§ 405.718d Expedited appeals process; effect of agreement.

The agreement described in § 405.718c, when signed, shall constitute a waiver by the parties and the Secretary with respect to the need of the parties to pursue the remaining steps of the administrative appeals process, and the period for filing a civil action in a district court of the United States, as provided in section 205(g) of the Social Security Act, shall begin as of the date on which the party (parties) and the authorized representative of the Secretary sign the agreement. Any civil action under the expedited appeals process must be filed within 60 days following the date on which the agreement is signed by, or on behalf of, the Secretary.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718e Effect of a request that does not result in agreement.

If a request for the expedited appeals process does not meet all the conditions for the use of the process, the Secretary shall so advise the party (parties) and shall treat the request as a request for reconsideration, a hearing, or Departmental Appeals Board review, whichever is appropriate.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 32348, June 24, 1996]

§ 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 Health Care Financing Administration;

(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]

§ 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 Social Security Administration or the Health Care Financing Administration or with a presiding officer, 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]

§ 405.724 Departmental Appeals Board review.

Departmental Appeals Board review is provided by 20 CFR 404.967.

[45 FR 73933, Nov. 7, 1980, as amended at 61 FR 32348, June 24, 1996]

§ 405.730 Court review.

To the extent authorized by section 1869, section 1876(f), and section 1879(d) of the Act, a party to a decision of the Departmental Appeals Board (see 20 CFR 404.979) or the decision of a presiding officer where the request for review by the Departmental Appeals Board was denied, may obtain a court review where the amount in controversy after Departmental Appeals Board review is $1,000 or more, 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 (see 20 CFR 422.210 for the filing procedure). A party to a reconsidered determination may obtain a court review where the amount in controversy is $1,000 or more and he requests and meets the conditions for the expedited appeals process (see § 405.718).

[45 FR 73933, Nov. 7, 1980, as amended at 61 FR 32348, June 24, 1996]

§ 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 presiding officer 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 presiding officer finds that the amount in controversy is less than $100, the presiding officer shall dismiss the request for hearing and will not rule on the substantive issues involved in the appeal.

§ 405.750 Time period for reopening initial, revised, or reconsidered determinations and decisions or revised decisions of a presiding officer or the Departmental Appeals Board; finality of determinations and decisions.

(a) *Reopenings concerning applications and entitlement.* A determination, or decision, or revised determination or decision made by the Social Security Administration 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 the Health Care Financing Administration, or a decision or revised decision of a presiding officer or of the Departmental Appeals Board, with respect to an individual's rights concerning a request for payment under Part A of Medicare, which is otherwise final 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]

§ 405.753 Appeal of a categorization of a device.

(a) HCFA'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) HCFA'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, HCFA'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), and 1869(b) of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b)).

SOURCE: 32 FR 18028, Dec. 16, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.801 Title XVIII, Part B—General.

(a) Section 1842(b)(3)(C) of the Act provides that a carrier shall establish and maintain procedures under which an individual enrolled in the supplementary medical insurance plan (see subpart B of this part) is provided with the opportunity for a hearing by the carrier when the amount in controversy is $100 or more as determined in accordance with § 405.820(b) and he is dissatisfied with the carrier's determination denying a request for payment, or with the amount of payment under the supplementary medical insurance plan or when he believes that the request for payment is not being acted upon with reasonable promptness. A physician or other person who furnishes items or services to a person enrolled under the supplementary medical insurance plan and who accepts an assignment from the enrollee has the same right as the enrollee to appeal the carrier's determination.

(b) As used in this section, the term *with reasonable promptness* shall mean a period of 60 consecutive days after the receipt by the carrier of a request for payment.

(c) Procedures governing determinations as to whether an individual is entitled to supplementary medical insurance, which implement section 1869(a) of the Social Security Act, are covered in subpart G of this part and 20 CFR part 404, subpart J.

[39 FR 12096, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 45 FR 73945, Nov. 7, 1980]

§ 405.802 Definitions.

As used in subpart H of this part, the term—

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.

[59 FR 12182, Mar. 16, 1994]

§ 405.803 Initial determination.

(a) The carrier (or the hearing officer where a claim is ''not acted upon with reasonable promptness'' (see § 405.801)) shall, on the basis of all of the evidence, make an initial determination with respect to an applicant's claim for benefits under Part B of title XVIII.

(b) An initial determination for purposes of this subpart includes among others, a determination as to whether items and services furnished are covered; whether the deductible has been met; whether the receipted bill or other evidence of payment is acceptable; whether the charges for items or services furnished are reasonable; and if the items or services furnished an enrollee by a physician or a supplier of services pursuant to an assignment under § 424.55 of this chapter are not covered by reason of § 405.310(k), whether such enrollee, physician, or supplier knew or could reasonably have been expected to know that such items or services were excluded from coverage.

(c) Carriers (or hearing officers where a claim is not acted upon with reasonable promptness (see § 405.801)) do not make determinations with respect to the following, which are not initial determinations for purposes of this subpart:

(1) Any issue or factor for which the Social Security Administration or the Health Care Financing Administration 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); or

(2) Any issue or factor which relates to hospital insurance benefits under Part A of title XVIII of the Act.

[39 FR 12097, Apr. 3, 1974, as amended at 40 FR 1026, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 59382, Dec. 20, 1978; 45 FR 73945, Nov. 7, 1980; 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988]

§ 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(b).

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.806 Effect of initial determination.

The initial determination shall be final and binding upon the party or parties to such determination unless it is reviewed in accordance with §§ 405.810 through 405.812, or is revised in accordance with § 405.841 by the carrier (or by the hearing officer presiding where a claim is not acted upon with reasonable promptness (see § 405.801)).

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.807 Review of initial determination.

(a) *General.* A party to an initial determination by a carrier, who is dissatisfied with such initial determination, may request that the carrier review such determination. If a review is requested, such action shall not constitute a waiver of the right to hearing (see § 405.820) subsequent to such review.

(b) *Place of filing request.* A request for a carrier to review the initial determination is to be made in writing and filed at an office of the carrier or at an office of the Social Security Administration or the Health Care Financing Administration.

(c) *Time of filing request.* The carrier shall provide a period of 6 months after the date of the notice of its initial determination within which a party to the initial determination may request review. The carrier may, upon request by the party affected, extend the period for requesting the review.

(d) *Request for review.* Any clear expression in writing by a party to an initial determination which indicates, in effect, that he is dissatisfied with such determination by the carrier and wants to appeal the matter further constitutes a request for review.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 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 final and 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]

§ 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 HCFA.

(c) Except when a carrier hearing is held because the carrier did not act upon a claim with reasonable promptness (see § 405.801), 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]

§ 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, and 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, and 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, and 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, and 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, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.831 Waiver of right to appear 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.

§ 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 final and 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, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.833 Record of carrier hearing.

A complete record of the proceedings at the hearing shall be made. The testimony shall be transcribed and copies of other documentary evidence shall be reproduced in any case when directed by the hearing officer, the carrier or

the Health Care Financing Administration. The record will also be transcribed and reproduced at the request of a party to the hearing provided he bears the cost thereof.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.834 Carrier hearing officer's decision.

As soon as practicable after the close of a hearing, the hearing officer, except as provided in this subpart, shall make a decision in the case which shall be based upon the evidence adduced at the hearing (see §§ 405.820 to 405.830) or otherwise included in the hearing record (see § 405.833). The decision shall be made in writing and contain findings of fact and statement of reasons. A copy of the decision shall be mailed to each party to the hearing at his last known address.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.835 Effect of carrier hearing officer's decision.

The hearing officer's decision, provided for in § 405.834, shall be final and binding upon all parties to the hearing unless it is revised in accordance with § 405.841.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 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 404.958); 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, and amended at 59 FR 12183, Mar. 16, 1994]

§ 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 final and 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]

§ 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.

§ 405.860 Authority of the carrier hearing officer.

The hearing officer in exercising the authority to conduct a hearing under section 1842(b)(3)(C) of the Act is to comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with policy statements, instructions and other guides issued by the Health Care Financing Administration in accordance

with the Secretary's agreement with the carriers.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 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 Social Security Administration or the Health Care Financing Administration or unless otherwise prohibited by law.

§ 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 HCFA, 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 HCFA, 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 HCFA.

(d) A HCFA official, designated by the Administrator of HCFA, must make an appeal decision based on the evidence presented to the fair hearing officer and his or her decision. The HCFA official requests any additional information he or she deems necessary from either the carrier or the entity within two weeks of receipt by the HCFA of the appeal. Notice of the HCFA official's decision—

(1) Is issued within two weeks of when the last information is received is

received by the HCFA 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 HCFA 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 HCFA 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 HCFA 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) HCFA'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) HCFA'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, HCFA'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]

Subparts I–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 HCFA.

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 § 405.374 concerning claims collection activities, the term does not include an action by HCFA 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, and 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]

§ 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, HCFA 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 recovery of overpayments.* The intermediary's determination as contained in its notice constitutes 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 the suspending of further payments to the provider in order to recover, or to aid in the recovery of, any overpayment identified in the determination to have been made to the provider, notwithstanding any request for hearing on the determination the provider may make under §405.1811 or §405.1835. Any suspension will remain in effect as specified in §405.373(a).

[48 FR 39834, Sept. 1, 1983, as amended at 49 FR 322, Jan 3, 1984; 51 FR 34793, Sept. 30, 1986]

§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, and 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 Health Care Financing Administration 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 Health Care Financing Administration (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 HCFA Rulings issued under the authority of the Administrator of the Health Care Financing Administration (see 42 CFR 401.108),

and with the general instructions issued by the Health Care Financing Administration 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, HCFA Rulings, and general instructions of the Health Care Financing Administration, 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 Health Care Financing Administration 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 Health Care Financing Administration 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 Health Care Financing Administration, 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 Health Care Financing Administration 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 Health Care Financing Administration.

§ 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 Health Care Financing Administration.

§ 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 HCFA Rulings issued under the authority of the Administrator of the Health Care Financing Administration (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 HCFA.

[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 HCFA 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 HCFA.

(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, and 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 HCFA.

(2) The Office of the Attorney Advisory will examine the Board's decisions, the requests made by a party or HCFA 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 HCFA 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 HCFA, the Administrator will normally consider whether it appears that:

(1) The Board made an erroneous interpretation of law, regulation or HCFA 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 HCFA 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 HCFA 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 HCFA has requested review, the Administrator will promptly notify the parties and HCFA 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 HCFA 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 HCFA, 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 HCFA, if HCFA 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 HCFA 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 HCFA, 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 HCFA 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 HCFA.

(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 HCFA.

(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) A determination or a hearing decision rendered by the intermediary shall be reopened and revised by the intermediary if, within the aforementioned 3-year period, the Health Care Financing Administration notifies the intermediary that such determination or decision is inconsistent with the applicable law, regulations, or general instructions issued by the Health Care Financing Administration in accordance with the Secretary's agreement with the intermediary.

(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) 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).

§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 HCFA.

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, and 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.

HCFA 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.* HCFA 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.

HCFA 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 HCFA 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 HCFA, 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 HCFA 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, and 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, and 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, and 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 HCFA Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244–1850 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. 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, and 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]

§ 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]

§ 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 HCFA Information Resources Center, 7500 Security Boulevard, Baltimore, MD 21244–1850 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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.* HCFA may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if HCFA 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 HCFA 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 HCFA 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.* HCFA 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 HCFA proposes to apply a sanction specified in § 405.2181(b), the following rules apply:

(a) HCFA gives the facility notice of the proposed sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, HCFA provides an informal hearing by a HCFA 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, HCFA 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 HCFA 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 HCFA to meet the requirements for receiving such a grant;

(3) Was treated by HCFA, 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.

HCFA stands for Health Care Financing Administration.

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 means a facility that:

(1) Has been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter; and

(2) Has filed an agreement with the Secretary in order to provide rural health clinic services under Medicare. (See §405.2402.)

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]

§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 HCFA 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 rural health clinic services begins only after the beneficiary has incurred the deductible.

(2) Medicare payment for services covered under the Federally qualified health center benefit is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* (1) The beneficiary is responsible for a coinsurance amount which cannot exceed 20 percent of the clinic's reasonable customary charge for the covered service; and

(2)(i) The beneficiary's deductible and coinsurance liability, with respect to any one item or service furnished by the rural health clinic, may not exceed a reasonable amount customarily charged by the clinic for that particular item or service.

(ii) For any one item or service furnished by a Federally qualified health center, the coinsurance liability may not exceed 20 percent of a reasonable amount customarily charged by the center for that particular item or service.

[57 FR 24976, June 12, 1992]

§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, HCFA 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 HCFA 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 HCFA 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) HCFA 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, HCFA sends the entity two copies of the agreement. The entity must sign and return both copies of the agreement to HCFA.

(4) If HCFA accepts the agreement filed by the Federally qualified health center, HCFA 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 HCFA as a Federally qualified health center.

(2) The PHS notifies HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA a written notice stating its intention to terminate the agreement; and

(2) Notifying HCFA 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, HCFA 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 HCFA; or

(ii) Except as specified in paragraph (2) of this section, a date set by HCFA, which is no later than 6 months after the date HCFA 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 HCFA's receipt of the Federally qualified health center's notice of intention to terminate if HCFA 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 HCFA.* (1) HCFA 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 HCFA.* HCFA 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 HCFA'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 HCFA, 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 HCFA.

When HCFA has terminated an agreement with a Federally qualified health center, HCFA will not enter into another agreement with the Federally qualified health center to participate in the Medicare program unless HCFA—

(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 HCFA terminates the agreement, HCFA 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 HCFA.* A center which is contemplating or negotiating change of ownership must notify HCFA.

(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 and Federally qualified health center services.

(a) *Payment to provider-based rural health clinics and Federally qualified health centers.* A rural health clinic or Federally qualified health center is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if:

(1) The clinic or center is an integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (i.e., a provider of services); and

(2) The clinic or center is operated with other departments of the provider under common licensure, governance and professional supervision.

(b) *Payment to independent rural health clinics and freestanding Federally qualified health centers.* (1) All other clinics and centers will be paid on the basis of an all-inclusive rate for each beneficiary visit for covered services. This rate will be determined by the intermediary, in accordance with this subpart and general instructions issued by HCFA.

(2) The amount payable by the intermediary for a visit will be determined in accordance with paragraph (b)(3) and (4) of this section.

(3) *Federally qualified health centers.* For Federally qualified health center visits, Medicare will pay 80 percent of the all-inclusive rate since no deductible is applicable to Federally qualified health center services.

(4) *Rural health clinics.* (i) If the deductible has been fully met by the beneficiary prior to the rural health clinic visit, Medicare pays 80 percent of the all-inclusive rate.

(ii) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the clinic's reasonable customary charge for the services that is applied to the deductible is—

(A) Less than the all-inclusive rate, the amount applied to the deductible will be subtracted from the all-inclusive rate and 80 percent of the remainder, if any, will be paid to the clinic;

(B) Equal to or exceeds the all-inclusive rate, no payment will be made to the clinic.

(5) To receive payment, the clinic or center must follow the payment procedures specified in section 410.165 of this chapter.

(6) Payment for treatment of mental psychoneurotic or personality disorders is subject to the limitations on payment in § 410.155(c).

§ 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 HCFA 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 HCFA, on the basis of costs estimated to be reasonable for the provision of such services.

[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]

§ 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 HCFA, 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 HCFA, and such other information as HCFA 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 HCFA, 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 HCFA 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, HCFA 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 HCFA'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 HCFA or at any Social Security branch or district office, are used to apply for Medicare entitlement under the circumstances indicated:

HCFA–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.)

HCFA–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.* Effective January 1, 1988, 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 24th month following the first month of SGA 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, and 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]

§ 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 HCFA 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.

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[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''.

(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.

(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 HCFA 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 HCFA, 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 HCFA'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 HCFA 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) HCFA 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, and 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) HCFA 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 ''HCFA 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 HCFA if HCFA 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, and 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, and 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 HCFA 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

Subpart A—General Provisions

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407.50 Continuation of coverage: Individual enrollment following end of coverage under a State buy-in agreement.

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 HCFA, or at any Social Security branch or district office, are used to apply for enrollment under the supplementary medical insurance program.

HCFA–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.)

HCFA–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.)

HCFA–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.)

HCFA–40–F—Application for Medical Insurance. (For use by beneficiaries residing outside the United States.)

HCFA–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 on 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 HCFA 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 HCFA 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.

(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 HCFA 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

[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.

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 HCFA 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 HCFA 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

[1] Rules for buy-in for premium hospital insurance for QMBs are set forth in § 406.26 of this chapter.

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.

(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 HCFA 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 HCFA 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 HCFA requests such an opinion.

(b) *Termination by HCFA.* If HCFA, after giving the State notice and opportunity for hearing, finds that the

[1] Rules for buy-in for premium hospital insurance for QMBs are set forth in §406.26 of this chapter.

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, HCFA 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, HCFA finds that there is no longer that failure to 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 HCFA 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

HCFA receives a State ineligibility notice later than the time specified in paragraph (c)(1) of this section. A notice received by HCFA 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 HCFA, 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 HCFA'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]

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. HCFA 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) HCFA 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.

(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.

(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]

§ 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 HCFA'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, HCFA 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, HCFA 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 HCFA 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) HCFA, 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 ''HCFA 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 HCFA 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 HCFA.

§ 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), HCFA 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 HCFA 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.* HCFA 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.

HCFA 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 HCFA.

(3) A group payer that is an entity of State or local government may retain the authorizations and certify to HCFA 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 HCFA 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) HCFA 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 HCFA 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 HCFA for the group payment process.

(c) *HCFA responsibilities.* HCFA—

(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) HCFA ordinarily refunds to the group payer the premiums specified in paragraph (a) of this section.

(2) However, if HCFA 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 HCFA upon 30 days' notice.

(b) HCFA 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 HCFA.

§ 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, HCFA notifies the group payer to discontinue payment for that enrollee.

(2) In order to maintain confidentiality, HCFA 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 HCFA and the enrollee.

(2) HCFA 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) HCFA 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), HCFA 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 HCFA and the circumstances under which HCFA 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, HCFA will attempt to collect unpaid premiums by one of the following methods:

(1) By billing enrollees who pay the premiums directly to HCFA 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.* HCFA 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 HCFA'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 HCFA's satisfaction, that the estate is unable to pay the debt within a reasonable time.

(d) *Renewal of collection efforts.* HCFA 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 HCFA has received premiums for months after the enrollee's death, HCFA 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, HCFA 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.

PART 409—HOSPITAL INSURANCE BENEFITS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (U.S.C. 1302 and 1895hh).

SOURCE: 48 FR 12541, Mar. 25, 1983, unless otherwise noted.

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 rural primary care hospital program.

(d) Section 1861 describes the services covered under Medicare Part A, and benefit periods.

(e) Section 1862(a) specifies exclusions from coverage; and section 1862(h) requires a registry of pacemakers.

(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]

§ 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 HCFA'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 HCFA 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 RPCH 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 Rural Primary Care 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 RPCH services'' means the following services furnished to an inpatient of a participating hospital or of a participating RPCH 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 RPCH facilities;

(4) Medical social services;

(5) Drugs, biologicals, supplies, appliances, and equipment;

(6) Certain other diagnostic or therapeutic services; and

(7) Medical or surgical services provided by certain interns or residents-in-training.

(b) *Inpatient hospital services* does not include SNF-type care furnished by a hospital or an RPCH that has a swing-bed approval, or any nursing facility-type care that may be furnished as a Medicaid service under title XIX of the Act.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, May 26, 1993]

§ 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 RPCH has no semiprivate or ward accommodations; or

(iii) The hospital's or RPCH'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 RPCH, respectively, for treatment of a condition that required immediate inpatient hospital or inpatient RPCH 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 RPCH 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 RPCH'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 RPCH facilities.

(a) Except as provided in paragraph (b) of this section, Medicare pays for nursing and related services, use of hospital or RPCH facilities, and medical social services as inpatient hospital or inpatient RPCH services only if those services are ordinarily furnished by the hospital or RPCH, 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 RPCH 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 RPCH services only if—

(1) They represent a cost to the hospital or RPCH;

(2) They are ordinarily furnished by the hospital or RPCH for the care and treatment of inpatients; and

(3) They are furnished to an inpatient for use in the hospital or RPCH.

(b) *Exception.* Medicare pays for a limited supply of drugs for use outside the hospital or RPCH 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 RPCH services only if—

(1) They are ordinarily furnished by the hospital or RPCH to inpatients; and

(2) They are furnished to inpatients for use in the hospital or RPCH.

(b) *Exceptions.* Medicare pays for items to be used beyond the hospital or RPCH stay if—

(1) The item is one that the beneficiary must continue to use after he or she leaves the hospital or RPCH, 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 RPCH 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 RPCH 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 RPCH services if—

(a) They are furnished by the hospital or RPCH, or by others under arrangements made by the hospital or RPCH;

(b) Billing for those services is through the hospital or RPCH; and

(c) The services are of a kind ordinarily furnished to inpatients either by the hospital or RPCH or under arrangements made by the hospital or RPCH.

[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.

§ 409.19 Services related to cardiac pacemakers and pacemaker leads.

(a) *Requirement.* (1) Providers that request or receive Medicare payment for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads must submit to HCFA the information required for the pacemaker registry.

(2) The required information is set forth under 21 CFR part 805 of the FDA regulations and must be submitted in accordance with general instructions issued by HCFA.

(b) *Denial of payment.* If HCFA finds that a provider has failed to comply with paragraph (a) of this section, HCFA denies payment for the implantation, removal, or replacement of any permanent cardiac pacemaker or pacemaker lead, effective 45 days after sending the provider written notice in accordance with paragraph (c) of this section.

(c) *Notice of denial of payment.* The notice of denial of payment—

(1) States the reasons for the determination;

(2) Grants the provider 45 days from the date of the notice to submit the information or evidence showing that the determination is in error; and

(3) Informs the provider of its right to hearing.

(d) *Right to hearing.* If the denial of payment determination goes into effect at the expiration of the 45-day period, it constitutes an ''initial determination'' subject to administrative and judicial review under part 498 of this chapter.

[56 FR 8840, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

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 RPCH 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) Certain medical services provided by an intern or resident-in-training;

(7) Certain other diagnostic or therapeutic services; and

(8) Other services that are necessary to the health of the patient and are generally provided 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 SNFs.* Except as specifically listed in §§ 409.22 through 409.27, only those services generally provided by SNFs are considered as posthospital SNF care. For example, if an individual is furnished the use of an operating room by a SNF, that service is not included as ''posthospital SNF care'' because SNFs generally do not maintain operating rooms.

(c) *Terminology.* In §§ 409.22 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 an RPCH with swing-bed approval under subpart F of part 485 of this chapter.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30667, May 26, 1993]

§ 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 Drugs and biologicals.

(a) 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.

§ 409.25 Supplies, appliances, and equipment.

(a) Except as specified in paragraph (b) of this section, Medicare pays for supplies, appliances, and equipment as posthospital SNF care only if—

(1) They are ordinarily furnished by the facility to inpatients; and

(2) They are furnished to inpatients for use in the facility.

(b) *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. Sterile dressings would be an example.

§ 409.26 Services furnished by an intern or a resident-in-training.

Medicare pays for medical services furnished by an intern or a resident-in-training as posthospital SNF care if—

(a) The intern or resident is in a participating hospital with which the SNF has in effect an agreement for the transfer of patients and exchange of medical records or in a hospital that has a swing-bed approval; and

(b) The intern or resident furnishes the services under a hospital teaching program approved in accordance with the provisions of § 409.15.

§ 409.27 Other diagnostic or therapeutic services.

Medicare pays for other diagnostic or therapeutic services as posthospital SNF care if they are provided by a participating hospital with which the SNF has in effect an agreement for the transfer of patients and exchange of clinical records, or by a hospital or an RPCH that has a swing-bed approval.

[58 FR 30667, May 26, 1993]

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 RPCH 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) *Pre-admission requirements.* The beneficiary must—

(1) Have been hospitalized in a participating or qualified hospital or participating RPCH, for medically necessary inpatient hospital or inpatient RPCH care, for at least 3 consecutive calendar days, not counting the day of discharge, or have received inpatient RPCH care for 72 hours; and

(2) Have been discharged from the hospital or RPCH 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 RPCH 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 RPCH.

(2) *Exception.* A beneficiary for whom posthospital SNF care would not be medically appropriate within 30 days after discharge from the hospital or RPCH may be admitted at the time it would be medically appropriate to begin an active course of treatment.

[48 FR 12541, Mar. 25, 1983, as amended at 51 FR 41338, Nov. 14, 1986; 58 FR 30666, 30667, May 26, 1993]

§ 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 RPCH services; or

(ii) Which arose while the beneficiary was receiving care in a SNF or swing-bed hospital for a condition for which he or she received inpatient hospital or inpatient RPCH services.

(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]

§ 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

[1] Before December 5, 1980, the law required that admission and receipt of care be within 14 days after discharge from the hospital or RPCH 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.

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.* 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. This would include the management of a plan involving only a variety of personal care services when, in light of the patient's condition, the aggregate of those services requires the involvement of technical or professional personnel. For 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 would support a finding that recovery and safety can be assured only if the total care is planned, managed, and evaluated by technical or professional personnel, it would be appropriate to infer that skilled services are being provided.

(2) *Observation and assessment of the patient's changing condition.* 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 for additional medical procedures until his or her condition is stabilized. For example, 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) which serve as indicators for adjusting therapeutic measures. Likewise, surgical patients transferred from a hospital to a skilled nursing facility while in the complicated, unstabilized postoperative period, e.g., 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, etc., may also require skilled observation and assessment by technical or professional personnel to assure their safety and/or

the safety of others, i.e., to observe for indications of suicidal or hostile behavior. The need for services of this type must be documented by physicians' orders and/or nursing or therapy notes.

(3) *Patient education services.* Patient education services are skilled services if the use of technical or professional personnel is necessary to teach a patient self-maintenance. For example, 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. Likewise, a patient newly diagnosed with diabetes requires instruction from technical or professional personnel to learn the self-administration of insulin or foot-care precautions, etc.

(b) *Services that qualify as skilled nursing services.* (1) Intravenous, intramuscular, or subcutaneous injections and hypodermoclysis or intravenous feeding;

(2) Levin tube and gastrostomy feedings;

(3) Nasopharyngeal and tracheostomy aspiration;

(4) Insertion and sterile irrigation and replacement of 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.

§ 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.* The plan of care must be signed and dated by a physician who meets the certification and recertification requirements of § 424.22 of this chapter. The plan of care must be signed by the physician before the bill for services is submitted. Any changes in the plan must be signed and dated by the 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.* 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 62 days. 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 62-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]

§ 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 RPCH, 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 RPCH, 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) An RPCH 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 §405.330 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 §405.330;

(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 if a Medicaid or Medicare claim was denied on grounds other than that the services were not at the skilled level of care;

(ii) 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 §405.330; or

(iii) 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]

§ 409.61 General limitations on amount of benefits.

(a) *Inpatient hospital or inpatient RPCH 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 RPCH 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 RPCH 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 RPCH 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 an RPCH with a swing–bed approval.* Up to 100 days are available in each benefit period after discharge from a hospital or RPCH. 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 RPCH 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:

[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.

(i) 80 percent of the reasonable cost of the service.

(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, RPCH, 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 RPCH 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 RPCH 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 RPCH 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 RPCH.

(2) The election may be filed at the time of admission to the hospital or RPCH 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 RPCH.

(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 RPCH 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 RPCH 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 RPCH, 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 RPCH, an election not to use lifetime reserve days must apply to the entire hospital or RPCH 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 RPCH 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 RPCH 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 RPCH services furnished before notification of exhaustion of benefits.

(a) *Conditions for payment.* Payment may be made for inpatient hospital or inpatient RPCH 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 HCFA or the intermediary notified the hospital or RPCH 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 RPCH 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 RPCH stay.

(4) The hospital or RPCH 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 RPCH is notified that the beneficiary has exhausted the available benefit days.

(c) *Recovery from the beneficiary.* Any payment made to a hospital or RPCH 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 RPCH or SNF services that Medicare does not pay.

(2) The hospital or RPCH 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 an RPCH 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 RPCH 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 RPCH 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 RPCH 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 RPCH 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 RPCH'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, Medicare pays hospital insurance benefits only to a participating provider.

(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.

§ 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 1395(hh)), unless otherwise indicated.

SOURCE: 51 FR 41339, Nov. 14, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 410.1 Basis and scope.

(a) *Statutory basis.* Section 1832 of the Social Security Act establishes the scope of benefits provided under the Medicare Part B supplementary medical insurance (SMI) program. Sections 1833, 1834, 1835, and 1862 set forth the amounts of payment for SMI services, the conditions for payment, and the exclusions from coverage. Section 1861 defines the kinds of services that may be covered. Section 1881 provides for

Medicare coverage for end stage renal disease patients.

(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]

§ 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 such admission;

(5) Provides consultation and education services; and

(6) Meets applicable licensing or certification requirements for CMHCs in the State in which it is located.

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 HCFA's satisfaction that a significant portion of its patients are low-income; and (2) requests that payment for its services be determined accordingly.

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, SNF, HHA, CORF, 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, 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]

§ 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 an RPCH, diagnostic tests, outpatient physical therapy and speech pathology services, rural health clinic services, Federally qualified health center 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]

§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 an RPCH.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or RPCH if the services are services that the hospital or RPCH 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.

[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]

§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]

§ 410.20 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.

§ 410.22 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 X-ray demonstrates that a subluxation exists and if the subluxation has resulted in a neuromusculoskeletal condition for which 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.

§ 410.23 Limitations on services of an optometrist.

The services of optometrists are covered only if related to the condition of aphakia (absence of the natural crystalline lens of the eye, regardless of whether an intraocular lens has been implanted). The following are examples of examination services that may be covered when furnished by optometrists:

(a) Case history (the determination of changing visual performance as it relates to the condition of aphakia).

(b) External examination (the inspection with illumination and magnification of eyelids and surrounding areas of the eye).

(c) Ophthalmoscopy (the inspection with illumination and magnification of the internal structure of the eye).

(d) Biomicroscopy (the inspection of frontal tissues of the eye, using illumination and magnification).

(e) Tonometry (the measurement of the internal pressure of the eye).

(f) Evaluation of visual fields (central and peripheral fields of vision).

(g) Evaluation of ocular motility (the determination of the ability of the eye to move efficiently).

(h) Evaluation of binocular function (the ability of the eye to obtain single, clear, two-eyed vision).

(i) Examination required to prescribe prosthetic lenses in connection with aphakia.

§ 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) Medicare Part B pays for services and supplies incident to a physician's professional services, including drugs and biologicals that cannot be self-administered, if the services or supplies are of the type that are commonly furnished in a physician's office or clinic, and are commonly furnished either without charge, or included in the physician's bill.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29.

§ 410.27 Outpatient hospital services and supplies incident to physicians' services: Conditions.

(a) Medicare Part B pays for hospital services and supplies furnished incident

[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.

to physicians' services 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; and

(ii) As an integral though incidental part of a physician's services; 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.

[56 FR 8841, Mar. 1, 1991]

§ 410.28 Hospital or RPCH diagnostic services furnished to outpatients: Conditions.

(a) Medicare Part B pays for hospital or RPCH 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 RPCH.

(2) They are ordinarily furnished by, or under arrangements made by, the hospital or RPCH to its outpatients for the purpose of diagnostic study.

(3) They would be covered as inpatient hospital services if furnished to an inpatient.

(4) If furnished under arrangements, they are furnished in the hospital or RPCH or in other facilities operated by or under the supervision of the hospital or its organized medical staff.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29(b) and (c).

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

[51 FR 41339, Nov. 14, 1986, as amended at 58 FR 30668, May 26, 1993]

§ 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]

§ 410.31 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]

§ 410.32 Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Diagnostic x-ray services*—(1) *Basic rule*. Except as provided in paragraphs (a)(2) and (a)(3) of this section, diagnostic x-ray tests are covered only if performed under the direct supervision of a physician who is a doctor of medicine, osteopathy, dental surgery, dental medicine, or podiatric medicine, or by a radiology department that meets the requirements for a hospital radiology department set forth at § 482.26 of this chapter. The term *direct supervision* means that the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time a technician is performing services.

(2) *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:

(i) These services are furnished under the general supervision of a physician. ''General supervision'' occurs when x-ray procedures are performed by technicians without direct physician supervision. However, the service must be performed under the physician's overall direction and control.

(ii) The supplier of these services meets the requirements set forth in part 405, subpart N of this chapter.

(3) *Diagnostic procedures*. Diagnostic x-ray procedures performed by technicians under general physician supervision are covered, if—

(i) The general supervision and training of the technicians, as well as the maintenance of the necessary equipment and supplies, are the continuing responsibility of the physician; and

(ii) The procedures are limited to skeletal films involving the extremities, pelvis, vertebral column or skull, and chest or abdominal films that do not involve the use of contrast media.

(b) *Diagnostic laboratory tests*. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following:

(1) A participating hospital or participating RPCH.

(2) 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.

(3) 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.

(4) A rural health clinic.

(5) A laboratory, if it meets the applicable requirements 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.

(6) A Federally qualified health center.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987, as amended at 55 FR 22790, June 4, 1990; 57 FR 7135, Feb. 28, 1992; 57 FR 24981, June 12, 1992; 58 FR 30668, May 26, 1993]

§ 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 paragraph (a)(2) 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 a woman over age 39, but under age 50, the following limitations apply:

(i) 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 if the woman has—

(A) A personal history of breast cancer;

(B) A personal history of biopsy-proven benign breast disease;

(C) A mother, sister, or daughter who has had breast cancer; or

(D) Not given birth before age 30.

(ii) If the woman does not meet the conditions described in paragraph (d)(4)(i) of this section, payment may be made for a screening mammography performed after at least 23 months have passed following the month in which the last screening mammography was performed.

(5) For a woman over age 49, but under age 65, 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.

(6) For a woman over age 64, payment may be made for a screening mammography performed after at least 23 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]

§ 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, HCFA 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]

§ 410.38 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 an RPCH 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 HCFA; 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 HCFA as requiring a seat-lift; and

(3) Meets safety requirements specified by HCFA.

(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, HCFA 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]

§ 410.40 Ambulance services: Limitations.

(a) *Definitions.* As used in this section—

Ambulance means a vehicle that—

(1) Is specially designed for transporting the sick or injured;

(2) Contains a stretcher, linens, first aid supplies, oxygen equipment, and other lifesaving equipment required by State or local laws; and

(3) Is staffed with personnel trained to provide first aid treatment.

Appropriate hospital, RPCH or SNF refers to a hospital, RPCH or SNF that is capable of providing the required level and type of care for the patient's illness or injury and, in the case of a hospital, has available the type of physician or physician specialist needed to treat the patient's condition.

Hospital inpatient or RPCH inpatient means a beneficiary who has been formally admitted to a hospital or RPCH and has not been formally discharged.

Locality means the service area, surrounding a hospital or RPCH or SNF, from which individuals normally come or are expected to come for hospital or RPCH or SNF services.

Outside supplier means a hospital or RPCH or a nonhospital treatment facility, such as a clinic, therapy center, or physician's office, where a hospital or SNF inpatient may be taken to receive medically necessary diagnostic or therapeutic services not available at the hospital or SNF where he or she is an inpatient.

(b) *Limits on coverage of ambulance transportation.* Medicare Part B pays for ambulance transportation only if—

(1) Other means of transportation would endanger the beneficiary's health;

(2) Medicare Part A payment is not available for the service; and

(3) In the case of a hospital inpatient and RPCH inpatient—

(i) The transportation is furnished by, or under arrangements made by, the hospital or RPCH; or

(ii) The transportation is furnished by an ambulance service with which the hospital does not have an arrangement (as defined in §409.3 of this chapter), and the hospital has a waiver (in accordance with §489.23 of this chapter) under which Medicare Part B payment may be made to the ambulance service.

(c) *Limits on origins and destinations.* Medicare Part B pays for ambulance transportation of a beneficiary—

(1) To a hospital or RPCH or SNF, from any point of origin;

(2) To his or her home, from a hospital or RPCH or SNF; or

(3) Round trip from a hospital or RPCH or a participating SNF to an outside supplier to obtain medically necessary diagnostic or therapeutic services not available at the hospital or RPCH or SNF where the beneficiary is an inpatient.

(d) *Specific limits on coverage of ambulance transportation outside the United States.* In the case of services furnished outside the United States, Medicare Part B pays only for ambulance transportation to a foreign hospital and only in conjunction with the beneficiary's admission for medically necessary inpatient services as specified in subpart H of part 424 of this chapter.

(e) *Limitation on payments.* Medicare payments for ambulance services within the United States are limited to the amounts that would be paid for transportation—

(1) To an appropriate hospital or RPCH or SNF in whose locality the beneficiary is located or, if the beneficiary is not in the locality of an appropriate hospital or RPCH or SNF, to the nearest appropriate hospital or RPCH or SNF;

(2) To the beneficiary's home from a hospital or RPCH or SNF in whose locality the home is located, or from the nearest appropriate hospital or RPCH or SNF; or

(3) Round trip to the nearest outside supplier capable of providing necessary diagnostic or therapeutic services not available at the hospital or RPCH or SNF where the beneficiary is an inpatient.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987, as amended at 53 FR 6648, Mar. 2, 1988; 58 FR 30668, May 26, 1993]

§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) Physicians' services that meet the criteria of part 405, subpart F of this chapter for payment on a fee schedule basis in accordance with part 414 of this chapter.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act, that are furnished after December 31, 1990.

(3) Clinical psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

[59 FR 6577, Feb. 11, 1994]

§ 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.

§ 410.50 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.

§ 410.57 Pneumococcal vaccine and its administration: Conditions.

Effective July 1, 1981, Medicare Part B pays for pneumococcal vaccine and its administration to a beneficiary, when reasonable and necessary for the prevention of disease, if the vaccine is ordered by a doctor of medicine or osteopathy.

§ 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.

§ 410.60 Outpatient physical therapy services: Conditions.

(a) *Basic rule.* Medicare Part B pays for outpatient physical therapy services if they meet 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, 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 independent practice who is licensed by the State in which he or she practices and who meets the qualifications specified in § 485.705(b) of this chapter.

(b) *Outpatient physical therapy services to certain inpatients of a hospital or an RPCH or SNF.* Medicare Part B pays for outpatient physical therapy services furnished to an inpatient of a hospital, RPCH 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 independent practice*—(1) *Who is a physical therapist in independent practice.* A physical therapist in independent practice is one who—

(i) Engages in the practice of physical therapy on a regular basis;

(ii) Furnishes services on his or her own responsibility without the administrative and professional control of an employer;

(iii) Maintains, at his or her own expense, office space and the necessary equipment to provide an adequate program of physical therapy;

(iv) Furnishes services only in office space maintained at his or her expense, or in the patient's home; and

(v) Treats individuals who are his or her own patients and collects fees or other compensation for the services furnished.

(2) *Limitation on incurred expenses.* (i) Before 1982, not more than $100 of reasonable charges incurred in a calendar year are recognized as incurred expenses.

(ii) From 1982 through 1989, not more than $500 of reasonable charges incurred in a calendar year are recognized as incurred expenses.

(iii) From 1990 through 1993, not more than $750 of reasonable charges incurred in a calendar year are recognized as incurred expenses.

(iv) After 1993, not more than $900 of reasonable charges incurred in a calendar year are recognized as incurred expenses.

(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 RPCH inpatient.

[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; 59 FR 26959, May 25, 1994; 60 FR 2329, Jan. 9, 1995]

§ 410.61 Plan of treatment requirements for outpatient physical therapy and speech pathology services.

(a) *Basic requirement.* Outpatient physical therapy services (including services furnished by a qualified physical therapist in independent practice), and outpatient speech pathology services 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]

(1) A physician.

(2) A physical therapist who will furnish the physical therapy services.

(3) A speech pathologist who will furnish the speech pathology services.

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy or speech 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 or the physical therapist or speech pathologist who furnishes the services.

(ii) A registered professional nurse or a staff physician, in accordance with oral orders from the physician, physical therapist, or speech pathologist who furnishes the services.

(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]

§ 410.62 Outpatient speech pathology services: Conditions and exclusions.

(a) *Basic rule.* Medicare Part B pays for outpatient speech pathology services if they meet 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—

[1] Before January 1981, only a physician could establish a plan of treatment for physical therapy or speech pathology service. Speech pathologists were authorized to establish a plan effective January 1, 1981; physical therapists, effective July 18, 1984.

(i) Is established by a physician or, effective January 1, 1982, by either a physician or the speech pathologist who will provide the services to the particular individual;

(ii) Is periodically reviewed by a physician; and

(iii) Meets the requirements of § 410.63.

(3) They are furnished by a provider or by others under arrangements with, and under the supervision of, a provider.

(b) *Outpatient speech pathology services to certain inpatients of a hospital, RPCH, or SNF.* Medicare Part B pays for outpatient speech pathology services furnished to an inpatient of a hospital, RPCH, or SNF who requires them 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 pathology service if it would not be included as an inpatient hospital service if furnished to a hospital or RPCH inpatient.

[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]

§ 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.* 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.

[55 FR 22790, Jun. 4, 1990; 55 FR 31186, Aug. 1, 1990]

§ 410.64 Services related to cardiac pacemakers and pacemaker leads.

(a) *Requirement.* (1) Physicians or providers that request or receive payment for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads, must submit to HCFA the information required for the pacemaker registry.

(2) The required information is set forth under 21 CFR part 805 of the FDA

regulations and must be submitted in accordance with general instructions issued by HCFA.

(b) *Denial of payment.* If HCFA finds that a physician or provider has failed to comply with paragraph (a) of this section, HCFA will deny payment for the implantation, removal, or replacement of any permanent cardiac pacemaker or pacemaker lead, effective 45 days after sending the physician or provider written notice in accordance with paragraph (c) of this section.

(c) *Notice of denial of payment.* The notice of denial of payment—

(1) States the reasons for the determination;

(2) Grants the physician or provider 45 days from the date of the notice to submit the information or evidence showing that the determination is in error; and

(3) Informs the physician or provider of its right to hearing.

(d) *Right to hearing.* If the denial of payment goes into effect at the expiration of the 45-day period, it constitutes an ''initial determination'' subject to administrative and judicial review under part 498 of this chapter.

[56 FR 8841, Mar. 1, 1991]

§ 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 weeks 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]

§ 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]

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]

Subparts F–H—[Reserved]

Subpart I—Payment of SMI Benefits

SOURCE: 51 FR 41339, Nov. 14, 1986. 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)(13) 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 rural primary care hospital (RPCH) on the individual's behalf for outpatient RPCH services furnished by the RPCH.

(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).

[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]

§ 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) In the case of physician and CORF services for the treatment of a mental, psychoneurotic, or personality disorder, furnished to an individual who is not an inpatient of a hospital, the expenses excluded from incurred expenses under § 410.155(c).

(v) In the case of expenses incurred for outpatient physical therapy furnished by therapists in independent practice, expenses in excess of $500 in reasonable charges incurred in a calendar year.

(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 HCFA.

(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 RPCH services.* (1) *General.* For services furnished by an RPCH to its outpatients, Medicare Part B payment is made under either one of the following methods elected by the RPCH.

(2) *Cost-based RPCH facility services payment plus professional medical services payment method.* Payment for RPCH facility services is made in accordance with § 413.70(b)(2)(i) of this chapter, and payment for professional medical services is made on a reasonable charge or other fee basis in accordance with § 413.70(b)(2)(ii) of this chapter and with the other provisions of this chapter that apply to payment for professional medical services when they are not included in outpatient RPCH services.

(3) *All-inclusive rate method.* Payment for both RPCH facility services and professional medical services is made at a single all-inclusive rate per visit, subject to the applicable Part B deductible and coinsurance amounts, as described in § 413.70(b)(3) of this chapter.

[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]

[1] For services furnished before July 1, 1987, Medicare Part B paid 100 percent of the standard amount.

§ 410.155 Outpatient mental health treatment limitation.

(a) *Definitions.* As used in this section, unless the context indicates otherwise, ''*Mental, psychoneurotic, or personality disorder*'' means the specific psychiatric conditions described in the American Psychiatric Association's Diagnostic and Statistical Manual—Mental Disorders. ''*Hospital*'' means any hospital that is primarily engaged in providing, by or under the supervision of physicians, diagnostic and therapeutic services for the medical diagnosis, treatment, and care of injured, disabled or sick persons, or rehabilitation services for the rehabilitation of injured, disabled or sick persons; or psychiatric services for the diagnosis and treatment of mentally ill persons; and medical services for the diagnosis and treatment of tuberculosis.

(b) *Services subject to limitation.* The mental health treatment limitation applies to the following services furnished for the treatment of a mental, psychoneurotic, or personality disorder, when the services are furnished to an individual who is not an inpatient in a hospital:

(1) CORF services.

(2) Physicians' services that meet the criteria of part 405, subpart F of this chapter for payment on a fee schedule basis in accordance with part 414 of this chapter.

(3) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act, that are furnished after December 31, 1990.

(4) Clinical psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

(c) *Limitation on incurred expenses*—(1) *Current limit.* For purposes of §§ 410.152 and 410.160, incurred expenses for the services specified in paragraph (b) of this section exclude expenses that are in excess of 62½ percent of the sum of the reasonable charges for physician services and the customary charges for CORF services.

(2) *Previous limits.* For years before calendar year 1990, incurred expenses that could be considered were limited to the lower of the current 62½ percent and a fixed dollar amount that—

(i) For calendar years before 1988, was $312.50;

(ii) For calendar year 1988, was $562.50; and

(iii) For calendar year 1989, was $1,375.

(d) *Example.*

As a private patient, Mr. X's only medical expenses during the calendar year 1982 amounted to $750 for physicians' services in connection with the treatment of a mental disorder which did not require inpatient hospitalization. The statutory limit for any calendar year on the amount of these expenses that is covered under this subpart B is $312.50 ($312.50 being lesser in amount than 62½ percent of $750). Mr. X is required to meet the first $75 as a deductible, and 20 percent of the balance. The remaining 80 percent is payable under this subpart B.

Total covered expenses	Mr. X's payment	Payment under subpart B
$312.50	[2] $437.50	
−75.00 [1]	[1] 75.00	
237.50	[3] 47.50	[4] 190.00

[1] Deductible, as described in § 409.360.
[2] In excess of $312.50.
[3] 20 percent of total covered expenses less deductible.
[4] 80 percent of total covered expenses less deductible.

If Mr. X had incurred $350 of the above expenses while an inpatient of an institution (see paragraph (b) of this section), and the remaining $400 while not an inpatient of an institution, payment would be computed as follows:

Total covered expenses	Mr. X's payment	Payment under subpart B
$250 [1]	[2] $150	
+350 [3]		
600	[4] 75	
−75		
525	[5] 105	[6] 420

[1] 62½ percent of $400.
[2] In excess of 62½ percent of $400.
[3] 100 percent of expenses incurred while an inpatient.
[4] Deductible.
[5] 20 percent of total covered expenses less deductible.
[6] 80 percent of total covered expenses less deductible.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8842, Mar. 1, 1991; 58 FR 30668, May 26, 1993; 59 FR 6578, Feb. 11, 1994]

§ 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.

(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 1982, the Part B annual deductible is $75.

(2) From 1973 through 1981, the deductible was $60.

(3) 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]

§ 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 RPCH, 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 HCFA.

(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 HCFA.

[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 HCFA form 1450 and in the manner prescribed by HCFA; 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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Subpart K—Payment for Certain Excluded Services

411.400 Payment for custodial care and services not reasonable and necessary.
411.402 Indemnification of beneficiary.
411.404 Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary.
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.
411.408 Refunds of amounts collected for physician services not reasonable and necessary, payment not accepted on an assignment-related basis.

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

SOURCE: 54 FR 41734, Oct. 11, 1989, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes affecting part 411 appear at 60 FR 45370, Aug. 31, 1995.

Subpart A—General Exclusions and Exclusion of Particular Services

§ 411.1 Basis and scope.

(a) *Statutory basis.* 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 Federal providers or agencies (sections 1814(c) and 1835(d)), by hospitals and physicians outside the United States (sections 1814(f) and 1862(a)(4)), and by hospitals and SNFs of the Indian Health Service (section 1880). Section 1877 sets forth limitations on referrals and payment for clinical laboratory services furnished by entities with which the referring physician (or an immediate family member of the referring physician) has a financial relationship. Sections 1842(l) and 1879 of the Act provide for refund to, or indemnification of, a beneficiary who has paid a provider or supplier for certain services that the provider or supplier knew were excluded from Medicare coverage.

(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]

§ 411.2 Conclusive effect of PRO determinations on payment of claims.

If a utilization and quality control peer review organization (PRO) 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 HCFA 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, symptom, complaint, or injury, except for screening mammography (including a physician's interpretation of the results) that meets the conditions for coverage and limitations on coverage of screening mammography specified at § 410.34 of this chapter and the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(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; and

(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.

(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 §§ 409.30 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.

[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.

(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.)

(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.

(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 inpatients.* (1) *Basic rule.* Except as provided in paragraph (m)(2) of this section, any service furnished to an inpatient of a hospital 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 inpatients. Services subject to exclusion under this paragraph include, but are not limited to, clinical laboratory services, pacemakers, artificial limbs, knees, and hips, intraocular lenses, total parenteral nutrition, and services incident to physicians' services. (As used in this paragraph (m)(1), the term ''hospital'' includes an RPCH.)

(2) *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) Certified nurse-midwife services, as defined in section 1861(ff) of the Act, that are furnished after December 31, 1990.

(iv) Qualified psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

(v) 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 PRO 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 non-experimental/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.

[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]

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 HCFA takes action to recover conditional payments, the beneficiary must cooperate in the action.

(b) If HCFA's recovery action is unsuccessful because the beneficiary does not cooperate, HCFA 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 HCFA. This information will be used only for Medicare claims processing and for coordination of benefits purposes.

(b) *Right to initiate recovery*. HCFA 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 HCFA to take legal action to recover, HCFA 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 HCFA to take legal action to recover from the primary payer, HCFA may recover twice the amount specified in paragraph (c)(1)(i) of this section.

(d) *Methods of recovery*. HCFA may recover by direct collection or by offset against any monies HCFA owes the entity responsible for refunding the conditional payment.

(e) *Recovery from third parties*. HCFA 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) HCFA 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, HCFA 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*. HCFA 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, HCFA 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, HCFA 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) HCFA 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, HCFA 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, HCFA charges interest in accordance with section 1862(b)(2)(B)(i) of the Act. Under that provision—

(i) HCFA 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 HCFA 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 HCFA and is charged until reimbursement is made; and

(iii) The rate of interest is that provided at 42 CFR 405.376(d).

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 60 FR 45361, 45362, Aug. 31, 1995]

§ 411.25 Third party payer's notice of mistaken Medicare primary payment.

(a) If a third party payer learns that HCFA 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 HCFA. 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, HCFA 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.* HCFA 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) HCFA 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 § 405.374 of this chapter.

(c) Other rules pertinent to recovery are contained in subpart C of part 405 of this chapter.

§ 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 HCFA 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 HCFA 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 HCFA seeks to recover.

(2) *Special rule.* If HCFA must file suit because the party that received payment opposes HCFA's recovery, the recovery amount is as set forth in paragraph (e) of this section.

(b) *Recovery against the third party payer.* If HCFA 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) *HCFA incurs procurement costs because of opposition to its recovery.* If HCFA must bring suit against the party that received payment because that party opposes HCFA'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 HCFA 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) *Basic rules*—(1) *Itemized bill.* A hospital must, upon request, furnish to the beneficiary or his or her representative an itemized bill of the hospital's charges.

(2) *Specific limitations.* Except as provided in paragraph (d) of this section, the provider or supplier—

(i) May not bill the liability insurer nor place a lien against the beneficiary's liability insurance settlement for Medicare covered services.

(ii) May only bill Medicare for Medicare-covered services; and

(iii) 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 the services) or under § 489.32 of this chapter (when services are partially covered).

(d) *Exceptions*—(1) *Nonparticipating suppliers.* The limitations of paragraph (c)(2) 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 has not claimed payment for them under § 424.64 of this chapter.

(2) *Prepaid health plans.* If the services were furnished through an organization that has a contract under section 1876 of the Act (that is, through 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.

(3) *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 limitations of paragraph (c)(2) of this section do not apply if the liability insurer pays within 120 days after the earlier of the following dates:

(A) The date the hospital 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 hospital must withdraw its claim or lien and comply with the limitations imposed by paragraph (c)(2) of this section.

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 HCFA 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, HCFA 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 HCFA determination that a GHP or LGHP is a nonconforming plan as provided in this section.

(b) HCFA 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) HCFA 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 HCFA 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 HCFA's ability to recover an erroneous primary payment.

§ 411.112 Documentation of conformance.

(a) *Acceptable documentation.* HCFA 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 HCFA any amount HCFA 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, HCFA 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.* HCFA'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 HCFA 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 HCFA determines that a GHP or an LGHP is nonconforming with respect to a particular calendar year, HCFA 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 HCFA the names and addresses of all employers and employee organizations that contributed to the plan during the calendar year for which HCFA has determined nonconformance.

(b) *Notice to contributing employers and employee organizations.* HCFA 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 HCFA 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 HCFA, the GHP or LGHP for which HCFA determined nonconformance, and any employers or employee organizations that contributed to the plan during the calendar year for which HCFA 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 HCFA'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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA.

§ 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 HCFA, 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 HCFA 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 HCFA Ruling; and

(2) Whether review may lead to the issuance of a HCFA 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 HCFA 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) *HCFA responsibility.* After HCFA 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 HCFA 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] (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

[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 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)).

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 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, HCFA 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.

[1] HCFA does not pay if noncoverage of services constitutes differentiation as prohibited by § 411.161(b).

(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:

(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-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:

[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. HCFA will modify the rules, if required, based on the final ruling by the court.

(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 HCFA 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.* HCFA 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 HCFA 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.* HCFA 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, HCFA 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.* HCFA 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 HCFA 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—Physician Ownership of, and Referral of Patients or Laboratory Specimens to, Entities Furnishing Clinical Laboratory or Other Health Services

SOURCE: 60 FR 41978, Aug. 14, 1995, 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 clinical laboratory 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 items or services under Part A or Part B report information concerning their ownership, investment, or compensation arrangements in the form, manner, and at the times specified by HCFA.

§ 411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

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. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Compensation arrangement means any arrangement involving any remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity.

Direct supervision means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

Employee means any individual who, under the usual 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 at 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Entity means a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association.

Fair market value means the value in arm's-length transactions, consistent with the general market value. With respect to rentals or leases, *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.

Financial relationship refers to a direct or indirect relationship between a physician (or a member of a physician's immediate family) and an entity in which the physician or family member has—

(1) An ownership or investment interest that exists in the entity through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing laboratory services; or

(2) A compensation arrangement with the entity.

Group practice means a group of two or more physicians, legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets the following conditions:

(1) Each physician who is a *member of the group,* as defined in this section, furnishes 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.

(2) Except as provided in paragraphs (2)(i) and (2)(ii) of this definition, 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) are furnished through the group and billed in the name of the group and the amounts received are treated as receipts of the group. ''Patient care services'' are measured by the total patient care time each member spends on these services. For example, if a physician practices 40 hours a week and spends 30 hours on patient care services for a group practice, the physician has spent 75 percent of his or her time providing countable patient care services.

(i) The ''substantially all'' test does not apply to any group practice that is located solely in an HPSA, as defined in this section, and

(ii) For group practices located outside of an HPSA (as defined in this section) any time spent by group practice members providing services in an HPSA should not be used to calculate whether the group practice located outside the HPSA has met the ''substantially all'' test, regardless of whether the members' time in the HPSA is spent in a group practice, clinic, or office setting.

(3) The practice expenses and income are distributed in accordance with methods previously determined.

In the case of faculty practice plans associated with a hospital, institution of higher education, or medical school that has an approved medical residency training program in which faculty practice plan physicians perform specialty and professional services, both within and outside the faculty practice, as well as perform other tasks such as research, this definition applies only to those services that are furnished within the faculty practice plan.

Hospital means any separate legally organized operating entity plus any subsidiary, related, or other entities that perform services for the hospital's patients and for which the hospital bills. A ''hospital'' does not include entities that perform services for hospital patients ''under arrangements'' with the hospital.

HPSA means, for purposes of this regulation, 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 42 CFR part 5, appendix A, part I—Geographic Areas). In addition, with respect to dental, mental health, vision care, podiatric, and pharmacy services, an HPSA means an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for dental professionals, mental health professionals, vision care professionals, podiatric professionals, and pharmacy professionals, respectively.

Immediate family member or member of a physician's immediate family means husband or wife; natural 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.

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.

Members of the group means physician partners and full-time and part-time

physician contractors and employees during the time they furnish services to patients of the group practice that are furnished through the group and are billed in the name of the group.

Patient care services means any tasks performed by a group practice member that address the medical needs of specific patients, regardless of whether they involve direct patient encounters. They can include, for example, the services of physicians who do not directly treat patients, time spent by a physician consulting with other physicians, or time spent reviewing laboratory tests.

Physician incentive plan means any compensation arrangement between an entity 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 items or services.

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, any item or 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.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of laboratory services or the establishment of a plan of care by a physician that includes the provision of laboratory services.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services if—

(i) The request is part of a consultation initiated by another physician; and

(ii) The tests or services are furnished by or under the supervision of the pathologist.

Referring physician means a physician (or group practice) who makes a referral as defined in this section.

Remuneration means any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration:

(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 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 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 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.

Transaction means an instance or process of two or more persons doing business. An *isolated transaction* is one involving a single payment between two or more persons. A transaction that involves long-term or installment payments is not considered an isolated transaction.

§ 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 financial relationship with an entity, or who has an immediate family member who has a financial relationship with the entity, may not make a referral to that entity for the furnishing of clinical laboratory services for which payment otherwise may be made under Medicare.

(b) *Limitations on billing.* An entity that furnishes clinical laboratory services under 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 clinical laboratory services performed under that referral.

(c) *Denial of payment.* No Medicare payment may be made for a clinical laboratory service that is furnished under a prohibited referral.

(d) *Refunds.* An entity that collects payment for a laboratory service that was performed under a prohibited referral must refund all collected amounts on a timely basis.

§ 411.355 General exceptions to referral prohibitions 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) *Physicians' services,* as defined in § 410.20(a), that are furnished personally by (or under the personal supervision of) another physician in the same group practice as the referring physician.

(b) *In-office ancillary services.* Services 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) Individuals who are directly supervised by the referring physician or, in the case of group practices, by another physician in the same group practice as the referring physician.

(2) They are furnished in one of the following locations:

(i) A building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services.

(ii) A building that is used by the group practice for the provision of some or all of the group's 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.

(iii) An entity that is wholly owned by the physician or the physician's group practice.

(c) *Services furnished to prepaid health plan enrollees by one of the following organizations:*

(1) An HMO or a CMP in accordance with a contract with HCFA 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 HCFA 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 the 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 health maintenance organization (within the meaning of section 1310(d) of the Public Health Service Act).

(d) *Services furnished in an ambulatory surgical center (ASC) or end stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

§ 411.356 Exceptions to referral prohibitions 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 may be

purchased on terms generally available to the public 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) In a corporation that had—

(i) Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding $100 million; or

(ii) 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.

(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:

(1) A laboratory that is located in a rural area (that is, a laboratory that is not located in an urban area as defined in § 412.62(f)(1)(ii) of this chapter) and that meets the following criteria:

(i) The laboratory testing that is referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the rural laboratory is either—

(A) Performed on the premises of the rural laboratory; or

(B) If not performed on the premises, the laboratory performing the testing bills the Medicare program directly for the testing.

(ii) Substantially all of the laboratory tests furnished by the entity are furnished to individuals who reside in a rural area. Substantially all means no less than 75 percent.

(2) A hospital that is located in Puerto Rico.

(3) A hospital that is located outside of Puerto Rico if one of the following conditions is met:

(i) The referring physician is authorized to perform services at the hospital, and the physician's ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

(ii) Until January 1, 1995, the referring physician's ownership or investment interest does not relate (directly or indirectly) to the furnishing of clinical laboratory services.

§ 411.357 Exceptions to referral prohibitions 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 and is signed by the parties and specifies the premises covered by the lease.

(2) The term of the agreement is at least 1 year.

(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, 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 lease are set in advance and are consistent with fair market value.

(5) The charges 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.

(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 and signed by the parties and specifies the equipment covered by the lease.

(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.

(3) The lease provides for a term of rental or lease of at least 1 year.

(4) The rental charges over the term of the lease 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 lease would be commercially reasonable even if no referrals were made between the parties.

(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 to a physician or immediate family member of the physician, including remuneration for specific physicians' services furnished to a nonprofit blood center, if the following conditions are met:

(i) The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.

(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

(iv) The term of the arrangement is for at least 1 year.

(v) The compensation to be paid over the term of the 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 the 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 between a physician and an entity, 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 in the entity.

(ii) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary under section 1876(i)(8)(A)(ii) of the Act, the plan complies with any requirements the

Secretary has imposed under that section.

(iii) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of paragraph (d)(2) of this section.

(3) Until January 1, 1995, the provisions in paragraph (d)(1) and (2) of this section do not apply to any arrangements that meet the requirements of section 1877(e)(2) or section 1877(e)(3) of the Act as they read before they were amended by the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66).

(e) *Physician recruitment.* Remuneration provided by a hospital to recruit a physician that is intended to induce the physician to relocate 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:

(1) The arrangement and its terms are in writing and signed by both parties.

(2) The arrangement is not conditioned on the physician's referral of patients to the hospital.

(3) The hospital does not determine (directly or indirectly) the amount or value of the remuneration to the physician based on the volume or value of any referrals the physician generates for the hospital.

(4) The physician is not precluded from establishing staff privileges at another hospital or referring business to another entity.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the conditions set forth in paragraphs (c)(2) and (c)(3) of this section are met with respect to an entity in the same manner as they apply to an employer. There can be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions which are specifically excepted under the other provisions in §§ 411.355 through 411.357.

(g) *Arrangements with hospitals.* (1) Until January 1, 1995, any compensation arrangement between a hospital and a physician or a member of a physician's immediate family if the arrangement does not relate to the furnishing of clinical laboratory services; or

(2) Remuneration provided by a hospital to a physician if the remuneration does not relate to the furnishing of clinical laboratory services.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which clinical laboratory services are provided by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services provided 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 December 19, 1989, and has continued in effect without interruption since then.

(3) With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with an agreement that is set out in writing and 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 services 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—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for other items or services that are furnished at a price that is consistent with fair market value.

§ 411.360 Group practice attestation.

(a) Except as provided in paragraph (b) of this section, a group practice (as defined in section 1877(h)(4) of the Act and § 411.351) must submit a written statement to its carrier annually to attest that, during the most recent 12-month period (calendar year, fiscal year, or immediately preceding 12-month period) 75 percent of the total patient care services of group practice members was furnished through the group, was billed under a billing number assigned to the group, and the amounts so received were treated as receipts of the group.

(b) A newly-formed group practice (one in which physicians have recently begun to practice together) or any group practice that has been unable in the past to meet the requirements of section 1877(h)(4) of the Act must—

(1) Submit a written statement to attest that, during the next 12-month period (calendar year, fiscal year, or next 12 months), it expects to meet the 75-percent standard and will take measures to ensure the standard is met; and

(2) At the end of the 12-month period, submit a written statement to attest that it met the 75-percent standard during that period, billed for those services under a billing number assigned to the group, and treated amounts received for those services as receipts of the group. If the group did not meet the standard, any Medicare payments made for clinical laboratory services furnished by the group during the 12-month period that were conditioned upon the standard being met are overpayments.

(c) Once any group has chosen whether to use its fiscal year, the calendar year, or some other 12-month period, the group practice must adhere to this choice.

(d) The attestation must contain a statement that the information furnished in the attestation is true and accurate and must be signed by a group representative.

(e) A group that intends to meet the definition of a group practice in order to qualify for an exception described in §§ 411.355 through 411.357, must submit the attestation required by paragraph (a) or paragraph (b)(1) of this section, as applicable, to its carrier no later than 60 days after receipt of the attestation instructions from its carrier.

[60 FR 41978, Aug. 14, 1995, as amended at 60 FR 63440, Dec. 11, 1995]

§ 411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing items or services for which payment may be made under Medicare must submit information to HCFA concerning their financial relationships (as defined in paragraph (d) of this section), in such form, manner, and at such times as HCFA specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that provide 20 or fewer Part A and Part B items and services during a calendar year, or to designated health services provided outside the United States.

(c) *Required information.* The information submitted to HCFA under paragraph (a) of this section must include at least the following:

(1) The name and unique physician identification number (UPIN) of each physician who has a financial relationship with the entity;

(2) The name and UPIN of each physician who has an immediate relative (as defined in § 411.351) who has a financial relationship with the entity;

(3) The covered items and services provided by the entity; and

(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, if requested by HCFA).

(d) *Reportable financial relationships.* For purposes of this section, a financial relationship is any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information on a HCFA-prescribed form within the time period specified by the servicing carrier or intermediary. Entities are given at

least 30 days from the date of the carrier's or intermediary's request to provide the initial information. Thereafter, an entity must provide updated information within 60 days from the date of any change in the submitted information. Entities must retain documentation sufficient to verify the information provided on the forms and, upon request, must make that documentation available to HCFA or the 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 of the period beginning on the day following the applicable 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 HCFA under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

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 PRO or the intermediary determines that the additional period of one day is necessary for planning post-discharge care. It the PRO 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.* Written notice has been 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. A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion. For example, program payment may not be made for the treatment of obesity, no matter what form the treatment may take. After the beneficiary who is treated for obesity with dietary control is informed in writing that Medicare will not pay for treatment of obesity, he or she will be presumed to know that there will be no Medicare payment for any form of subsequent treatment of this condition, including use of a combination of exercise, machine treatment, diet, and medication.

(c) *Source of notice.* The notice was given by one of the following:

(1) The PRO, 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.

§ 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 PRO, intermediary or carrier.* The PRO, 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 HCFA notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or PROs, including notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical

[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.

procedures subject to preadmission review by a PRO.

(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).

SOURCE: 50 FR 12741, Mar. 29, 1985, unless otherwise noted.

Subpart A—General Provisions

§ 412.1 Scope of part.

(a) *Purpose.* 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 § 413.86 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.

(b) *Summary of content.* This subpart describes the basis of payment for inpatient hospital services under the prospective payment systems, and sets forth the general basis of these systems. Subpart B of this part sets forth the classifications of hospitals that are included in and excluded from the prospective payment systems, and sets forth requirements governing the inclusion or exclusion of hospitals in the systems as a result of changes in their classification. Subpart C sets forth certain conditions that must be met for a hospital to receive payment under the prospective payment systems. Subpart D sets forth the basic methodology by which prospective payment rates for inpatient operating costs are determined. Subpart E describes the transition rate-setting methods that are used to determine transition payment rates for inpatient operating costs during the first four years of the prospective payment system. Subpart F sets forth the methodology for determining additional payments for outlier cases. Subpart G sets forth rules for special treatment of certain facilities under the prospective payment system for inpatient operating costs. Subpart H describes the types, amounts, and methods of payment to hospitals under the prospective payment system for inpatient operating costs. Subpart K describes how the prospective payment system for inpatient operating costs is implemented for hospitals located in Puerto Rico. Subpart L sets forth the procedures and criteria concerning applications from hospitals to the Medicare Geographic Classification Review Board for geographic redesignation. Subpart M describes how the prospective payment system for inpatient capital-related costs is implemented effective with cost reporting periods beginning on or after October 1, 1991.

[57 FR 39818, Sept. 1, 1992, as amended at 58 FR 46337, Sept. 1, 1993]

§ 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 have an atypically long length of stay or 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.

(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) Certain preadmission services furnished by the hospital or by an entity wholly owned or operated by the hospital (that is, any entity for which the hospital itself is the sole owner or operator) to the patient during the 3 days immediately preceding the date of the patient's admission to the hospital. A hospital is considered the sole operator of an entity if the hospital has exclusive responsibility for conducting or overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity. The specific preadmission services (other than ambulance services) included in the inpatient hospital operating costs are the following:

(i) Diagnostic services (including clinical diagnostic laboratory tests) furnished on or after January 1, 1991.

(ii) Other services related to the admission furnished on or after October 1, 1991. Other services related to the admission means services (other than diagnostic services) that are furnished in connection with the principal diagnosis that requires the beneficiary to be admitted as an inpatient.

(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) Heart, kidney, liver, and lung acquisition costs 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 rates for inpatient operating costs 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 § 413.86 of this chapter.

(8) For discharges on or after June 19, 1990, and before October 1, 1994, a payment amount per unit for blood clotting factor provided to Medicare inpatients who are hemophiliacs.

[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]

§ 412.4 Discharges and transfers.

(a) *Discharges.* A hospital inpatient is considered discharged when any of the following occurs:

(1) The patient is formally released from the hospital. (Release of the patient to another hospital as described in paragraph (b) of this section, or a leave of absence from the hospital, will not be recognized as a discharge for the purpose of determining payment under the prospective payment systems.)

(2) The patient dies in the hospital.

(3) The patient is transferred to a hospital or unit that is excluded from the prospective payment systems under subpart B of this part.

(b) *Transfers.* Except as provided under paragraph (a)(3) of this section, a discharge of a hospital inpatient is not counted for purposes of the prospective payment systems when the patient is transferred—

(1) From one inpatient area or unit of the hospital to another area or unit of the hospital;

(2) From the care of a hospital paid under this section to the care of another such hospital; or

(3) From the care of a hospital paid under this section to the care of another hospital—

(i) That is excluded from the prospective payment systems because of participation in an approved statewide cost control program or demonstration; or

(ii) Whose first cost reporting period under the prospective payment systems has not yet begun.

(c) *Payment in full to the discharging hospital.* The hospital discharging an inpatient (under paragraph (a) of this section) is paid in full, in accordance with § 412.2(b).

(d) *Payment to a hospital transferring an inpatient to another hospital.* (1) A hospital that transfers an inpatient under the circumstances described in paragraph (b)(2) or (b)(3) 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, E, 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 rates (as determined under subparts D, E, and M of this part) by the average length of stay for the specific Diagnosis-Related Group (DRG) into which the case falls. Payment is graduated by paying twice the per diem amount for the first day of the saty, and the per diem amount for each subsequent day, up to the limit described in paragraph (d)(1) of this section.

(2) However, if a discharge is classified into DRG No. 385 (Neonates, died or transferred) or DRG No. 456 (Burns, transferred to another acute care facility), the transferring hospital is paid in accordance with § 412.2(b).

(3) 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.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 30172, July 24, 1985; 57 FR 39819, Sept. 1, 1992; 60 FR 45846, Sept. 1, 1995]

§ 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.* HCFA 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) For cost reporting periods beginning after September 30, 1984, HCFA publishes an annual document setting forth the methodology and data used, including the percentage increase factor, to determine prospective payment rates for inpatient operating costs and (for cost reporting periods beginning after September 30, 1991) for inpatient capital-related costs applicable to discharges occurring during the Federal fiscal year beginning on or after October 1 of that year.

(2) HCFA 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 May 1 before the beginning of the Federal fiscal year in which the proposed changes would apply.

(3) HCFA publishes a FEDERAL REGISTER document setting forth final methods, amounts, and factors for determining inpatient prospective payment rates not later than the September 1 before the Federal fiscal year in which the rates would apply.

[57 FR 39820, Sept. 1, 1992]

§ 412.10 Changes in the DRG classification system.

(a) *General rule.* HCFA 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.* HCFA 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.* HCFA issues interim coverage changes through its administrative issuance system and makes the change effective as soon as is administratively feasible.

(3) *Publication for comment.* HCFA 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.* HCFA 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.* HCFA 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 paragraph (b) of this section, all covered inpatient hospital services furnished to beneficiaries during subject cost reporting periods are paid for under the prospective payment systems.

(b) Inpatient hospital services will not be paid for under the prospective payment systems 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 HCFA 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]

§ 412.22 Excluded hospitals and hospital units: General rules.

(a) *Criteria.* A hospital is excluded from the prospective payment systems if it meets the criteria for one or more of the excluded classifications described in § 412.23.

(b) *Cost reimbursement.* Except for those hospitals specified in paragraph (c) of this section, 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 described 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.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 57 FR 39820, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994]

§ 412.23 Excluded hospitals: Classifications.

Hospitals that meet the requirements for the classifications set forth in this section may not be reimbursed under the prospective payment systems.

(a) *Psychiatric hospitals.* A psychiatric hospital must—

(1) 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

(2) 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:

(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 exclusion for its first 12-month cost reporting period, as described in paragraph (b)(8) of this section, show that during its most recent 12-month cost reporting period, it served an inpatient population of whom at least 75 percent required intensive rehabilitative services for the treatment of one or more of the following conditions:

(i) Stroke.

(ii) Spinal cord injury.

(iii) Congenital deformity.

(iv) Amputation.

(v) Major multiple trauma.

(vi) Fracture of femur (hip fracture).

(vii) Brain injury.

(viii) Polyarthritis, including rheumatoid arthritis.

(ix) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.

(x) Burns.

(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 exclusion 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 such a 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 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, HCFA adjusts payments to the hospital retroactively in accordance with the provisions in § 412.130 of this part.

(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 paragraphs (e)(1) and (e)(2) of this section, and, where applicable, the additional requirements in paragraph (e)(3) of this section.

(1) The hospital must have a provider agreement under part 489 of this chapter to participate as a hospital.

(2) The hospital must have an average length of inpatient stay greater than 25 days—

(i) As computed by dividing the number of total inpatient days (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period;

(ii) If a change in the hospital's average length of stay is indicated, as computed by the same method for the immediately preceding 6-month period; or

(iii) 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 preceding 6 months, the hospital may be excluded from the prospective payment system as a long-term care hospital for a cost reporting period if, for 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.

(3) Except as provided in paragraph (e)(4) of this section, for cost reporting periods beginning on or after October 1, 1994, a hospital that occupies space 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, must meet the following criteria:

(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 bylaws 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 administrative authority flows, and who exercises control and surveillance over all administrative activities of the hospital. The chief executive office 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, and 482.42 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 length-of-stay criterion in paragraph (e)(2) of this section, the cost of the services that the hospital 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, 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, however, the costs of preadmission services are those specified under § 413.40(c)(2) rather than those specified under § 412.2(b)(5).

(C) For the same period of at least 6 months used to determine compliance with the length-of-stay criterion in paragraph (e)(2) of this section, 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.

(4) If a hospital has been excluded from the prospective payment systems under this paragraph for any cost reporting period beginning on or after October 1, 1993, but before October 1, 1994, the criteria in paragraph (e)(3) of this section do not apply to the hospital until the hospital's first cost reporting period beginning on or after October 1, 1995.

(5) 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.

(f) *Cancer hospitals.* 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, except that a hospital

classified after December 19, 1989 is excluded beginning with its first cost reporting period beginning after the date of its classification:

(1) 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.

(2) 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.

(3) 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).

(4) 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.)

(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).

[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]

§ 412.25 Excluded hospital units: Common requirements.

(a) *Basis for exclusion.* In order to be excluded from the prospective payment system, 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 exclusion from the prospective payment systems under this section, the number of beds and square footage of each excluded unit remains the same throughout each cost reporting period, and any change in the number of beds or square footage considered to be part of an excluded unit may be made only at the start of a cost reporting period.

(c) *Changes in the status of hospital units.* For purposes of exclusion from the prospective payment systems under this section, the status of each hospital unit (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 a unit are made only at the start of a 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 the hospital's next 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.

[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]

§ 412.27 Excluded psychiatric units: Additional requirements.

In order to be excluded from the prospective payment systems, 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 Third Edition 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]

§ 412.29 Excluded rehabilitation units: Additional requirements.

In order to be excluded from the prospective payment systems, 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(b).

(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]

§ 412.30 Exclusion of new rehabilitation units and expansion of units already excluded.

(a) *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 (a)(2) of this section is effective for the first full cost reporting period during which the unit is used to provide hospital inpatient care. If the hospital has not previously participated in the Medicare program as a hospital, the written certification 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.

(4) 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.

(b) *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 12-month cost reporting period, an inpatient population of which at least 75 percent required intensive rehabilitation services for the treatment of one or more conditions listed under § 412.23(b)(2).

(c) *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 number of beds the hospital seeks to add to its excluded rehabilitation unit is greater than 50 percent of the number of beds by which the hospital's State licensed and Medicare certified bed capacity increased under paragraph (c)(1)(i) of this section.

(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 (c)(1) of this section.

(ii) A hospital may increase the size of its excluded rehabilitation unit through conversion of existing bed capacity only if it shows that, for all of the hospital's most recent cost reporting period of at least 12 months, the beds have been used to treat an inpatient population meeting the requirements of § 412.23(b)(2).

(d) *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), HCFA 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]

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, HCFA 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 PRO. Concurrence by the PRO 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 PRO, 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 PRO 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 PRO 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

PRO 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 PRO 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 PRO.

(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 PRO 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 PRO or intermediary in accordance with HCFA 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 PRO to have the PRO 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 HCFA determines, on the basis of information supplied by a PRO 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, HCFA 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 PRO 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 HCFA 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, other than physicians' services to individual patients reimbursable on a reasonable charge basis (in accordance with the criteria of § 415.102(a) of this chapter).

(b) HCFA does not pay any provider or supplier other than the hospital for services furnished to a beneficiary who is an inpatient, except for physicians' services reimbursable under § 405.550(b) of this chapter and services of an anesthetist employed by a physician reimbursable under § 415.102(a) of this chapter.

(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]

§ 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.* HCFA establishs a classification of inpatient hospital discharges by Diagnosis-Related Groups (DRGs).

(b) *DRG weighting factors.* HCFA 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.* HCFA establishs 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. HCFA'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 PRO 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, HCFA 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.* HCFA 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.* HCFA 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.* HCFA 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.* HCFA 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.* HCFA 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.* HCFA adjusts each of the average standardized amounts determined under paragraphs (c), (d), and (e) of this section by factors representing HCFA'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.* HCFA 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 HCFA) 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) HCFA 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 peer review 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, HCFA 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.* HCFA adjusts the proportion (as estimated by HCFA 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 HCFA) 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 fiscal years after Federal fiscal year 1984.

(a) *General rule.* (1) HCFA determines a national adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge in a Federal fiscal year after fiscal year 1984 involving inpatient hospital services of a hospital in the United States subject to the prospective payment system, and determines a regional adjusted prospective payment 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 in paragraphs (b) through (g) of this section.

(b) *Geographic classifications.* (1) For purposes of this section, the definitions set forth in § 412.62(f) apply.

(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 HCFA, 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) HCFA computes an average standardized amount for hospitals in urban areas and rural areas within the United States, and urban areas and rural areas within each region.

(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 HCFA) 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. HCFA 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 HCFA) 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 HCFA) 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 HCFA 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 year 1987 onward, HCFA restandardizes the average standardized amounts by excluding an estimate of indirect medical education payments.

(6) For fiscal year 1988 and thereafter, HCFA 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 Bureau of the Census.

(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 and for subsequent years.* The applicable percentage change for fiscal year 1998 and for subsequent years is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) for all areas.

(q) *Maintaining budget neutrality for fiscal year 1985.* (1) For fiscal year 1985, HCFA 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 peer review organization, as allowed under section 1866(a)(1)(F) of the Act.

(r) *Computing Federal rates for inpatient operating costs for hospitals located in large urban and other areas.* For each discharge classified within a DRG, HCFA 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.

(s) *Adjusting for different area wage levels.* (1) HCFA adjusts the proportion (as estimated by HCFA 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 HCFA 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) HCFA makes a midyear correction to the wage index for an area only if a hospital can show that—

(A) The intermediary or HCFA made an error in tabulating the hospital's 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) Revisions to the wage index resulting from midyear corrections to the wage index values are incorporated in the wage index values for other areas at the beginning of the next Federal fiscal year.

(4) The effect on program payments of midyear corrections to the wage index values is taken into account in establishing the standardized amounts for the following Federal fiscal year.

(5) If a judicial decision reverses a HCFA denial of a hospital's wage data revision request, HCFA pays the hospital by applying a revised wage index that reflects the revised wage data as if HCFA's decision had been favorable rather than unfavorable.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 16786, May 6, 1986; 51 FR 31496, Sept. 3, 1986; 51 FR 34793, Sept. 30, 1986; 51 FR 42234, Nov. 24, 1986; 52 FR 23834, June 25, 1987; 52 FR 33057, Sept. 1, 1987; 53 FR 38527, Sept. 30, 1988; 55 FR 15173, Apr. 20, 1990; 55 FR 36069, Sept. 4, 1990; 56 FR 572, Jan. 7, 1991; 56 FR 9633, Mar. 7, 1991; 57 FR 39822, Sept. 1, 1992; 58 FR 46337, Sept. 1, 1993; 59 FR 45397, Sept. 1, 1994; 60 FR 45847, Sept. 1, 1995; 61 FR 46224, Aug. 30, 1996; 61 FR 51217, Oct. 1, 1996]

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 HCFA 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, HCFA 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 HCFA), 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 and following.* For Federal fiscal years 1996 and following, the update factor is 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, HCFA 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, HCFA 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.

[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]

§ 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)(5) through (c)(12).

(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 HCFA 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.

[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]

§ 412.76 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 HCFA 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]

Subpart F—Payment for Outlier Cases

§ 412.80 General provisions.

(a) *Basic rule.* (1) For discharges before October 1, 1994, except as provided in paragraph (a)(2) of this section concerning transferring hospitals, HCFA provides for additional payment, approximating a hospital's marginal cost of care beyond thresholds specified by HCFA, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if either of the conditions specified in paragraphs (a)(1)(i) and (a)(1)(ii) of this section is met. For discharges occurring on or after October 1, 1994, except as provided in paragraph (a)(2) of this section concerning transferring hospitals, HCFA 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 conditions specified in paragraphs (a)(1)(i) and (a)(1)(iii) of this section 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 HCFA.

(B) A fixed number of standard deviations, as specified by HCFA.

(ii) For discharges occurring before October 1, 1994, 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, effective with cost reporting periods beginning on or after October 1, 1991, capital costs, by applying cost-to-charge ratios as described in § 412.84(h), exceed the greater of the following:

(A) A fixed dollar amount (adjusted for geographic variation in costs) as specified by HCFA.

(B) A fixed multiple of the Federal operating rate and, effective with cost reporting periods beginning on or after October 1, 1991, a fixed multiple of the Federal capital prospective rate as determined under § 412.308.

(iii) For discharges occurring on or after October 1, 1994, 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 HCFA.

(2) *Outlier cases in transferring hospitals.* HCFA provides cost outlier payments to a transferring hospital that does not receive payment under § 412.2(b) for discharges specified in § 412.4(d)(2), if the hospital's charges for covered services furnished to the beneficiary, adjusted to cost by applying a national cost/charge ratio, exceed the greater of the criteria specified in paragraph (a)(1)(ii) of this section.

(b) *Publication and revision of outlier criteria.* HCFA will issue threshold criteria for determining outlier payment in the annual notice of prospective payment rates published in accordance with § 412.8(b).

(c) *Relation to hospitals that incur indirect costs for graduate medical education programs and that serve a disproportionate share of low-income patients.* The outlier payment amounts are included in total DRG revenue for purposes of determining payments to hospitals that incur indirect costs for graduate medical education programs under § 412.105 and to hospitals that serve a disproportionate share of low-income patients under § 412.106.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 16787, May 6, 1986; 51 FR 31496, Sept. 3, 1986; 53 FR 38529, Sept. 30, 1988; 57 FR 3016, Jan. 27, 1992; 57 FR 39822, Sept. 1, 1992; 59 FR 45398, Sept. 1, 1994]

§ 412.82 Payment for extended length-of-stay cases (day outliers).

(a) 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 PRO must review and approve to the extent required by HCFA—

(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. HCFA 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]

§ 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)(1)(ii).

(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 PRO 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 PRO 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 PRO determines that appropriate corrective actions have been taken.

(f) The PRO 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. The costs are adjusted further to exclude an estimate of indirect medical education costs and payments for hospitals that service a disproportionate share of low-income patients.

(h) The operating cost-to-charge ratio and, effective with cost reporting periods beginning on or after October 1, 1991, the capital cost-to-charge ratio 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. 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. HCFA sets forth these parameters and the statewide cost-to-charge ratios in each year's annual notice of prospective payment rates published under § 412.8(b).

(i) 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.

(j) Except as provided in paragraph (k) 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).

(k) 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 (j) 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.

[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]

§ 412.86 Payment for extraordinarily high-cost day outliers.

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]

Subpart G—Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Operating Costs

§ 412.90 General rules.

(a) *Sole community hospitals.* HCFA 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.* HCFA 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) *Christian Science Sanatoria.* HCFA may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital is a Christian Science sanatorium. Such a sanatorium's prospective payment rates are determined in accordance with § 412.98.

(d) *Kidney acquisition costs incurred by hospitals approved as renal transplantation centers.* HCFA 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 that are located in urban areas and that are reclassified as rural.* HCFA adjusts the rural Federal payment amounts for inpatient operating costs for hospitals reclassified as rural, as defined in § 412.62(f). The criteria for this adjustment are set forth in § 412.102.

(f) *Hospitals that have a high percentage of ESRD beneficiary discharges.* HCFA 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.* HCFA 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, HCFA 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) *Medicare-dependent, small rural hospitals.* For cost reporting periods beginning on or after April 1, 1990 and ending before April 1, 1993, HCFA 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. Criteria for identifying these hospitals are set forth in § 412.108.

(j) *Essential access community hospitals (EACH).* If a hospital meets the criteria of § 412.109 for designation as an EACH, HCFA 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]

§ 412.92 Special treatment: Sole community hospitals.

(a) *Criteria for classification as a sole community hospital.* HCFA 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 § 412.83(b)) 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 50 mile radius of the hospital or, if larger, within the hospital's service area, the hospital may request that HCFA 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 HCFA 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 HCFA.

(v) HCFA 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 HCFA's written notification of approval.

(ii) When a court order or a determination by the Provider Reimbursement Review Board (PRRB) reverses an

HCFA 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 HCFA'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 HCFA 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 HCFA'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 which is maintained by a local, State, or Federal government entity and which is available for use by the general public.

(2) The term *like hospital* means a hospital furnishing short-term, acute care. HCFA will not evaluate comparability of specialty services in making determinations on classifications as sole community hospitals.

(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 § 412.63, subject to the regional floor defined in § 412.70(c)(6).

(ii) The hospital-specific rate as determined under § 412.73.

(iii) The hospital-specific rate as determined under § 412.75.

(2) *Adjustments to payments.* A sole community hospital may receive an

adjustment to its payments to take into account a significant decrease in number of discharges or a significant increase in inpatient operating costs, as described in paragraphs (e) and (g) of this section respectively.

(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]

§ 412.96 Special treatment: Referral centers.

(a) *Criteria for classification as a referral center: Basic rule.* HCFA 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 § 412.63(b)) 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 § 412.62(f)) 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.* HCFA 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 HCFA uses to calculate these criteria is described in paragraph (g) 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 HCFA from the hospital's own billing records for Medicare discharges as processed by the fiscal intermediary and submitted to HCFA. 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 Federal fiscal year that ended 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 HCFA or the median case-mix index value for urban hospitals located in each region. In calculating the median case-mix index for each region, HCFA excludes the case-mix indexes of hospitals receiving indirect medical education payments as provided in § 412.105.

(2) *Number of discharges.* (i) HCFA 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 HCFA uses to calculate these criteria is described in paragraph (h) 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) [Reserved]

(f) *HCFA review of referral center status.* (1) *General rule.* The status of each hospital that is receiving a referral center adjustment is reviewed by the HCFA regional office every 3 years to determine if the hospital continues to meet the applicable criteria.

(2) *Retention criteria.* To retain referral center status, a hospital must meet the applicable criteria—

(i) In at least 2 of the last 3 years; or

(ii) For the current year.

(g) *Cancellation of referral center status.* (1) *General rule.* Referral center status can be cancelled by HCFA under the criteria in paragraph (g)(2) of this section or by the hospital under the criteria in paragraph (g)(3) of this section.

(2) *HCFA cancellation of referral center status.* If a hospital does not meet either of the retention criterion in paragraph (f)(2) of this section and no longer qualifies for a referral center adjustment, HCFA discontinues the adjustment beginning on the first day of the hospital's next cost reporting period beginning on or after October 1, 1994.

(3) *Hospital cancellation of referral center status.* (i) 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 § 412.63 as adjusted by the hospital's area wage index value.

(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 referral center status be cancelled, 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.* HCFA calculates the national and regional case-mix index value criteria as described in paragraphs (g)(1) through (g)(4) of this section.

(1) *Updating process.* HCFA 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 (g)(1) of this section, HCFA uses all inpatient hospital bills received for discharges

subject to prospective payment during the Federal fiscal year being monitored.

(3) *Effective date.* HCFA 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.

(4) *Applicability of criteria to HCFA review of referral center status.* For purposes of the triennial HCFA review of a referral center's status as described in paragraph (f) of this section, the referral center's case-mix index value for a Federal fiscal year is evaluated using the appropriate case-mix value criteria published in the annual notice of prospective payment rates.

(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, HCFA calculates the criteria as follows:

(1) *Updating process.* HCFA 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 (h)(1) of this section, HCFA uses the most recent hospital admissions or discharge data available.

(3) *Annual notice.* HCFA 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.

(4) *Applicability of criteria to HCFA review of referral center status.* For purposes of the triennial review of a referral center's status as described in paragraph (f) of this section, the referral center's number of discharges for its most recently completed cost reporting period is evaluated using the appropriate discharge criteria published in the annual notice of prospective payment rates.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §412.96, see the List of Sections Affected in the Finding Aids section of this volume.

§412.98 Special treatment: Christian Science Sanatoria.

(a) *General rule.* If a Christian Science Sanatorium is not excluded from the prospective payment systems under subpart B of this part, HCFA pays, for inpatient hospital services furnished to a beneficiary by that sanatorium, a predetermined fixed amount per discharge based on the sanatorium's historical inpatient operating costs per discharge.

(b) *Prospective payment rates.* For cost reporting periods beginning on or after October 1, 1983, the sanatorium's prospective payment rate for inpatient operating costs equals the amount that would constitute the sanatorium's target amount under §413.40(c)(4) of this chapter if the institution were subject to the rate of increase ceiling specified in §413.40 of this chapter instead of the prospective payment systems. This amount is not adjusted for the DRG weighting factor.

(c) *Outlier payments.* A Christian Science sanatorium is not eligible for outlier payments under subpart F of this part.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 57 FR 39823, Sept. 1, 1992; 58 FR 46338, Sept. 1, 1993; 59 FR 1658, Jan. 12, 1994]

§412.100 Special treatment: Renal transplantation centers.

(a) *Adjustments for renal transplantation centers.* (1) HCFA 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, work-up, 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]

§ 412.102 Special treatment: Hospitals reclassified as rural.

Effective on or after October 1, 1983, a hospital reclassified as rural, as defined in § 412.62(f), 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]

§ 412.104 Special treatment: Hospitals with high percentage of ESRD discharges.

(a) *Criteria for classification.* Effective with cost reporting periods that begin on or after October 1, 1984, HCFA provides an additional payment to a hospital for inpatient dialysis provided to ESRD beneficiaries if the hospital has established that ESRD beneficiary discharges, excluding discharges classified into DRG No. 302 (Kidney Transplant), DRG No. 316 (Renal Failure) or DRG No. 317 (Admit for Renal Dialysis), constitute ten 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]

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

HCFA makes an additional payment to hospitals for indirect medical education costs using the following procedures:

(a) *Basic data.* HCFA determines the following for each hospital:

(1) The hospital's ratio of full-time equivalent residents, except as limited under paragraph (g) of this section, to number of beds (as determined in paragraph (b) of this section).

(2) 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, but excluding additional payments made under the provisions of this subpart.

(b) *Determination of 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, not including beds or bassinets in the healthy newborn nursery, custodial care beds, or beds in excluded distinct part hospital units, and dividing that number by the number of days in the cost reporting period.

(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.* For discharges occurring on or after October 1, 1988, each hospital's education adjustment factor is calculated as follows:

(e) *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.

(f) *Count of residents for cost reporting periods beginning before July 1, 1991.* For cost reporting periods beginning before July 1, 1991, in order to have residents included in the count under paragraph (a)(1) of this section, the following requirements must be met:

(1) The residents must be enrolled in a teaching program approved under § 413.85 of this chapter (excluding those employed by the hospital, but furnishing services at another site).

(2) The hospital must submit an annual report to its fiscal intermediary. The report must include the following information:

(i) A listing, by specialty, of all residents assigned to the hospital and providing services to the hospital on September 1 of that year. If September 1 falls on a weekend or a Federal holiday, the next business day is used for purposes of the count of residents. For cost reporting periods beginning on or after October 1, 1984 and before July 1, 1985, the hospital must also report this information for April 15, 1985.

(ii) The social security number of each resident.

(iii) The hospital unit or department to which each resident is assigned on the day of the count.

(3) No resident will be counted as more than one full-time employee on the date counted, regardless of the number of hospitals in which he or she is providing services.

(4) Fiscal intermediaries must verify the correct count of residents and may review the hospital's entire cost reporting period.

(5) Residents who are assigned to a setting other than the inpatient or outpatient department of the hospital (such as a freestanding family practice center or an excluded hospital unit) on the day that the count of interns and residents (as described in paragraph (f)(2)(i) of this section) is made are not counted as full-time equivalents. Only the percentage of time that these residents spend in the portion of the hospital subject to the prospective payment system or in the outpatient department of the hospital on the day the count is made is used to determine the indirect medical education adjustment.

(6) Residents in anesthesiology who are employed to replace anesthetists are not counted as full-time equivalents.

(7) Based on its review of a hospital's documentation concerning the hospital's count of interns and residents under this section, the intermediary may adjust the resident-to-bed ratio for purposes of the final indirect medical education payment.

(g) *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 § 415.200(a) of this chapter.

(B) May count towards certification of the participant in a specialty or subspecialty listed in the Directory of Residency Training Programs published by the American Medical Association.

(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) For discharges occurring on or after August 10, 1993, any entity receiving a grant under section 330 of the Public Health Service Act that is under the ownership or control of the hospital (if the hospital incurs all, or substantially all, of the costs of the services furnished by those residents).

(iii) 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 of the areas of the hospital listed in paragraph (g)(1)(ii) of this section, to the total time worked by the resident. A part-time resident or one working in an area of the hospital other than those listed under paragraph (g)(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 (g)(1)(ii) of this section, compared to the total time necessary to fill a full-time internship or residency slot.

(iv) Residents in anesthesiology who are employed to replace anesthetists are not included in the count.

(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 (g)(1)(ii) of this section.

(3) Fiscal intermediaries must verify the correct count of residents.

[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 in the Finding Aids section of this volume.

§ 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) The number of patient days includes only those days attributable to areas of the hospital that are subject to the prospective payment system and excludes all others.

(iii) The hospital's location, in an urban or rural area, is determined in accordance with the definitions in § 412.62(f).

(2) The payment adjustment is applied to the hospital's total DRG revenues for inpatient operating costs.

(i) A hospital's total DRG revenues for inpatient operating costs are determined on the basis of DRG-adjusted prospective payment rates for inpatient operating costs or, for transition period payments under subpart B of this part, on the basis of the Federal portion of the hospital's payment rates.

(ii) For purposes of this section, total DRG revenues for inpatient operating costs include outlier payments for inpatient operating costs under subpart F of this part, but exclude additional payments made under this subpart.

(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, HCFA—

(i) Determines the number of covered 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 HCFA use its cost reporting period instead of the Federal fiscal year, it must furnish to HCFA, 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 hospital's cost reporting period, the number of patient days furnished to patients entitled to Medicaid but not to

Medicare part A, and divides that number by the total number of patient days in that same period.

(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, 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 of this subpart.

(iii) 40 percent, if the hospital is located in an urban area and has fewer than 100 beds.

(iv) 45 percent, 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.* (1) *Method of adjustment.* If a hospital serves a disproportionate number of low-income patients, its total 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, the payment adjustment factor is 4 percent plus 60 percent of the difference between the hospital's disproportionate patient percentage and 30 percent.

(B) If the hospital is classified as a sole community hospital, the payment adjustment factor is 10 percent.

(C) If the hospital is classified as both a rural referral center and a sole

community hospital, the payment adjustment factor is the greater of 10 percent or 4 percent plus 60 percent of the difference between the hospital's disproportionate patient percentage and 30 percent.

(D) If the hospital is not classified as either a sole community hospital or a rural referral center, the payment adjustment factor is 4 percent.

(iii) If the hospital meets the criteria of paragraph (c)(1)(iii) of this section, the payment adjustment factor is equal to 5 percent.

(iv) If the hospital meets the criteria of paragraph (c)(1)(iv) of this section, the payment adjustment factor is 4 percent.

(v) If the hospital meets the criteria of paragraph (c)(2) of this section, the payment adjustment factor is as follows:

(A) 30 percent for discharges occurring on or after April 1, 1990 and before October 1, 1991.

(B) 35 percent for discharges occurring on or after October 1, 1991.

[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]

§ 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, a hospital is classified as a Medicare-dependent, small rural hospital if it is located in a rural area (as defined in § 412.63(b)) and meets all 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 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.

(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.* The fiscal intermediary determines whether a hospital meets the criteria in paragraph (a) of this section. If a hospital disagrees with an intermediary's decision, it should notify its intermediary and submit documentable evidence that it meets the criteria.

(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 § 412.63, 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, 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) HCFA 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.

[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]

§ 412.109 Special treatment: Essential access community hospitals (EACHs).

(a) *General rule.* For payment purposes, HCFA 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 HCFA designates as an EACH under the criteria in paragraph (c) of this section. 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 § 412.63;

(3) Is not classified as an urban hospital for purposes of the standardized payment amount by HCFA 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) *Criteria for HCFA designation.*

(1) HCFA designates a hospital as an EACH if the hospital is located in a State that has received a grant under section 1820(a)(1) of the Act or in an adjacent State and is designated as an EACH by the State that has received the grant.

(2) HCFA designates a hospital as an EACH if—

(i) The hospital—

(A) Is not eligible for State designation as an EACH solely because the hospital has fewer than 75 inpatient beds and is located 35 miles or less from any other hospital; and

(B) Is located more than 35 miles from the nearest hospital having 75 or more inpatient beds, and is recommended by the State for designation as the EACH member of a proposed network; or

(ii) The following criteria are met—

(A) The hospital seeking EACH designation has entered into a network agreement under § 485.603 of this chapter with a facility that the State has designated as an RPCH, and the hospital designated as an RPCH by the State does not have a network agreement with any existing EACH;

(B) The facility that the State has designated as an RPCH, and that has entered into the network agreement described in paragraph (c)(2)(ii)(A) of this section, is located more than 35 miles from any other hospital having 75 or more inpatient beds;

(C) The distance between the facility that the State has designated as an RPCH and the hospital seeking designation as an EACH is less than the distance between the facility that the State has designated as an RPCH and the nearest hospital that has 75 or more inpatient beds or is designated as an EACH;

(D) The State certifies to HCFA that—

(*1*) The rural health network emergency and medical backup services actually being provided by the hospital seeking EACH designation are essential to the continued existence of the facility as a RPCH; and

(*2*) The existence of the facility as an RPCH is needed to ensure access to health care services in the area of the State served by the RPCH.

For purposes of this paragraph (c)(2)(ii), the location of a hospital will not be considered unless the hospital participates in Medicare under §§ 482.1 through 482.57 of this chapter.

(d) *Criteria for State designation.* A State that has received a grant under section 1820(a)(1) of the Act may designate as an EACH any hospital in the State or in an adjoining State that meets the criteria of this paragraph (d).

(1) *Geographic location.* The hospital meets one of the following requirements:

(i) If it is located in a rural area as described in paragraph (b) of this section, the hospital is located more than 35 miles from any hospital that either has been designated as an EACH, or has been classified as a rural referral center under § 412.96.

(ii) The hospital meets other criteria relating to geographic location, imposed by the State with HCFA's approval.

(2) *Bed capacity and location.* The hospital has at least 75 inpatient beds or is located more than 35 miles from any other hospital.

(3) *Agreements with RPCHs.* The hospital has in effect agreements with the RPCHs that participate in the rural health network (as defined in § 485.603 of this chapter) of which the hospital is a member, to—

(i) Provide emergency and medical backup services to RPCHs participating in the rural health network of which it is a member and throughout its service area;

(ii) Accept patients transferred from an RPCH;

(iii) Receive data from, and transmit data to, the RPCHs; and

(iv) Grant staff privileges to physicians who furnish care at the RPCHs.

(4) *Other requirements.* The hospital meets any other requirements imposed by the State with HCFA's approval.

(e) *Adjustment to the hospital-specific rate for rural EACH's experiencing increased costs.* (1) *General rule.* HCFA 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 HCFA within 60 days of receipt from the hospital:

(i) The hospital's documentation and the intermediary's verification of that documentation.

(ii) Its 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) *HCFA determination.* HCFA 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. HCFA 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.

(f) *Termination of EACH designation under paragraph (c)(2)(ii)(D).* If HCFA determines that the criteria in paragraph (c)(2)(ii)(D) of this section are no longer met with respect to a hospital HCFA has designated as an EACH under that paragraph, HCFA will terminate the EACH designation of the hospital, effective with discharges occurring on or after 30 days after the date of the determination.

(g) *Review of HCFA Determination.* A determination by HCFA that a hospital does not meet the criteria for EACH designation, or 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]

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.

[56 FR 43448, Aug. 30, 1991, as amended at 57 FR 39824, Sept. 1, 1992]

§ 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 § 413.86 of this chapter.

(3) Except as provided in § 413.86(c) of this chapter, 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 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 by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologist's assistants) employed by the hospital 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 by qualified nonphysician anesthetists employed by the hospital or obtained under arrangement, if the hospital demonstrates to its intermediary prior to April 1, 1989 that it meets the following criteria:

(A) The hospital 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 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. The hospital 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 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 has agreed in writing not to bill on a reasonable charge basis for his or her patient care in that hospital.

(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 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.

(iii) A hospital that did not qualify for reasonable cost payment for nonphysician anesthetist services furnished in calendar year 1989 can qualify for reasonable cost payment in subsequent calendar years, if it meets the criteria in § 412.113(c)(2)(i) (A), (B) and (D) above, and demonstrates to its intermediary prior to the start of the calendar year that it met these criteria. The hospital 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.

(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) *Heart, kidney, liver, and lung acquisition costs incurred by hospitals with approved transplantation centers.* Payment for heart, kidney, liver, and lung acquisition costs incurred by hospitals with approved transplantation centers is made on a reasonable cost basis.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.113, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 412.115 Additional payments.

(a) *Bad debts.* An additional payment is made to each hospital in accordance with § 413.80 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 on or after June 19, 1990, and before October 1, 1994, an additional payment is made to a hospital for each unit of blood clotting factor furnished to a Medicare inpatient who is hemophiliac.

(c) *PRO photocopy and mailing costs.* An additional payment is made to a hospital in accordance with § 466.78 of this chapter for the costs of photocopying and mailing medical records requested by a PRO.

[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]

§ 412.116 Method of payment.

(a) *General rule.* 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. Payments for inpatient hospital services furnished by an excluded psychiatric or a rehabilitation unit of a hospital are made as described in § 413.64 (a), (c), (d), and (e) of this chapter.

(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 payments.* Payments for outlier cases (described in subpart F of this part) are not made on an interim basis. The outlier 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 HCFA.

(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]

§ 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 system 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) 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 had a unit excluded from the prospective payment system 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 that 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.* The intermediary adjusts the payment to the hospitals described in paragraph (a) of this section as follows:

(1) 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, and the amount that would have been paid under the prospective payment systems for services furnished during that period.

(2) 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.

[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]

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 Payments to hospitals located in Puerto Rico.

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—

(a) 75 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.210; and

(b) 25 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

[57 FR 39825, Sept. 1, 1992]

§ 412.208 Puerto Rico rates for Federal fiscal year 1988.

(a) *General rule.* HCFA 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, HCFA 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.* HCFA 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.* HCFA 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.* HCFA 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.* HCFA 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 HCFA) 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, HCFA 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.* HCFA adjusts the proportion (as estimated by HCFA 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 HCFA) 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 fiscal years after Federal fiscal year 1988.

(a) *General rule.* (1) HCFA determines the Puerto Rico adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge occurring in a Federal fiscal year after fiscal year 1988 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 HCFA, 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.* HCFA 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 HCFA) 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, HCFA 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.* HCFA adjusts the proportion (as estimated by HCFA 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 HCFA) 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 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]

§ 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 a national average standardized amount.* HCFA computes a discharge-weighted average of the—

(1) National urban adjusted standardized amount determined under § 412.63(j)(1)(i); and

(2) National rural adjusted average standardized amount determined under § 412.63(j)(2)(i).

(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.* HCFA adjusts the proportion (as estimated by HCFA 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 HCFA) 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]

§ 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) *Purpose.* Except as provided in paragraph (a)(5) of this section, 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, wage index value, or both.

(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 §§ 412.230(b)(1) and (2), (d)(2), (e)(1)(iii), and (e)(l)(iv) (A) and (B), rounding of numbers to meet the mileage or qualifying percentage standard 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 for purposes of the standardized amount if the area to which the hospital seeks redesignation does not have a higher standardized amount than the standardized amount the hospital currently receives.

(iii) A hospital may not be redesignated to more than one area.

(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 an area's standardized amount for inpatient operating costs.* (1) *Criteria.* To receive an area's standardized amount for inpatient operating costs, a hospital must demonstrate that its incurred costs are more comparable to the amount it would be paid

if it were reclassified than the amount it would be paid under its current classification, and that it has the necessary geographic relationship (as specified in paragraphs (a) and (b) of this section) with the area to which it seeks redesignation.

(2) *Demonstrating comparable costs.* A hospital demonstrates that its costs are more comparable to the amount it would be paid if it were reclassified if the hospital's case mix adjusted cost per discharge is at least equal to its current rate plus 75 percent of the difference between that rate and the rate it would receive if it were reclassified.

(3) *Appropriate cost data.* For a standardized amount for inpatient operating costs change, the hospital must submit appropriate data as follows:

(i) For hospital-specific data, the hospital must provide data from its most recently settled and most recently filed cost report.

(ii) For data on other hospitals, the hospital must base its application on the most recent revisions to the prospective payment rates for inpatient operating costs, as published in the FEDERAL REGISTER.

(e) *Use of urban or other rural area's wage index.* (1) *Criteria for use of area's wage index.* 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) 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; and

(iv) One of the following conditions apply:

(A) 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; or

(B) The hospital's average hourly wage weighted for occupational categories is at least 90 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 data as follows:

(i) For hospital-specific data, the hospital must provide data from the HCFA 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 data of other hospitals, the hospital must provide data concerning the following:

(A) 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 HCFA 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 and;

(B) If the hospital is requesting reclassification under § 412.230(e)(1)(iv)(B), occupational-mix data to demonstrate the average occupational mix for each employment category in the area to which the hospital seeks reclassification. Occupational-mix data can be obtained from surveys conducted by the American Hospital Association.

[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]

§ 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 must be adjacent to the MSA or NECMA 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 hospitals may be redesignated only if one of the following conditions is met:

(i) The pre-reclassified average hourly wage for the area to which they seek redesignation is higher than the pre-reclassified average hourly wage for the area in which they are currently located.

(ii) 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.* 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.

(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.* The aggregate average 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 hospital-specific data, the hospitals must provide data from the HCFA 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.

(ii) For data for other hospitals, the hospitals must provide the following:

(A) The average hourly wage in the adjacent area, which is taken from the HCFA 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.

(B) 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.

[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]

§ 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) The county 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.

(4) The hospitals may be redesignated only if one of the following conditions is met.

(i) The pre-reclassified average hourly wage for the area to which they seek redesignation is higher than the pre-reclassified average hourly wage for the area in which they are currently located.

(ii) The standardized amount for the area to which they seek redesignation is higher than the standardized amount for the area in which they are currently 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 or NECMA to which the hospitals in the county seek reclassification; or

(2) *Aggregate hourly wage weighted for occupational mix.* The aggregate average hourly wage of all hospitals in the urban county, weighted for occupational categories, is at least 90 percent of the occupationally adjusted hourly wage, in the MSA or NECMA to which the hospitals in the county seek reclassification.

(c) *Standardized amount inpatient operating costs.*(1) *Criteria.* The urban hospitals must demonstrate that their average incurred costs are more comparable to the amount the hospitals would be paid if they were reclassified than the amount they would be paid under their current classification.

(2) *Demonstrating comparable costs.* The urban hospitals demonstrate that their costs are more comparable to the average amount they would be paid if they were reclassified if, on average, each hospital's case-mix adjusted cost per case is at least equal to the amount it would be paid under its current classification plus 75 percent of the difference between that amount and the amount the hospital would receive if it were reclassified.

(d) *Appropriate data.* (1) *Wage data.* The hospitals must submit appropriate wage data as provided for in § 412.230(e)(2).

(2) *Cost data.* The hospitals must submit appropriate data as provided for in § 412.230(d)(3).

[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]

§ 412.236 Alternative criteria for hospitals located in an NECMA.

(a) *General.* (1) An urban hospital whose designation is affected by the implementation of NECMAs may qualify for redesignation by meeting either the criteria in § 412.230 or the criterion in paragraph (b) of this section.

(2) All the hospitals in a NECMA may qualify for redesignation by meeting the criteria in either § 412.234 or in paragraph (c) of this section.

(b) *Criterion applicable to an individual urban hospital in a NECMA.* The hospital demonstrates that it would have been designated in a different urban area under the criteria for designating MSAs in New England.

(c) *Criteria applicable to a group of hospitals in a NECMA.* (1) All prospective payment hospitals in a NECMA must apply for redesignation.

(2) The hospitals must demonstrate that the NECMA to which they are designated would be combined as part of the NECMA to which they seek redesignation if the criteria for combining NECMAs were the same as the criteria used for combining MSAs.

(d) *Appropriate data.* (1) The MGCRB only considers population and commuting data developed by the Bureau of the Census.

(2) To meet the criterion in paragraph (b) of this section or the criteria in paragraph (c) of this section, hospitals must submit data from the Bureau of the Census.

[55 FR 36766, Sept. 6, 1990. Redesignated and amended at 56 FR 25488, June 4, 1991]

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 HCFA 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 HCFA.

[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 or in a NECMA agree to the request.

§ 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 HCFA, 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 Federal fiscal year 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 HCFA, 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 October 1.

(2) At the request of the hospital, the MGCRB may, for good cause, grant a

hospital that has submitted an application by October 1, an extension beyond October 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 HCFA, 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]

§ 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) HCFA 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 HCFA's comments to submit written comments to the MGCRB, with a copy to HCFA, for the purpose of responding to HCFA'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 HCFA, 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 HCFA.

§ 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. HCFA 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 HCFA. If such communication occurs, the MGCRB will disclose it to the hospital or HCFA, as appropriate, and make it part of the record after the hospital or HCFA 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 HCFA 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.* HCFA 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.

(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 HCFA'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) *Written request only.* A request to withdraw an application must be made in writing to the MGCRB by all hospitals that are party to the application.

(c) *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]

§ 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) *Application filed before October 1.* With the exception of the situation described in paragraph (b)(2) of this section, any classification change is effective for one 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) *Application filed on October 1.* If the complete application is filed on October 1, the redesignation is effective for discharges occurring on the first day of the following Federal fiscal year.

(c) *Additional decisions.* When the MGCRB determines that the facts that provide the basis for reclassification will remain unchanged through the end of the following Federal fiscal year, it may also provide for the following:

(1) A one-year automatic renewal of its decision.

(2) An abbreviated application and decision process for renewals.

§ 412.276 Timing of MGCRB decision and its appeal.

(a) *Timing.* The MGCRB notifies the parties in writing, with a copy to HCFA, and issues a decision within 180 days after the first day of the Federal fiscal year 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.

§ 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 HCFA's Office of Payment Policy.

(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, HCFA 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 HCFA's submission, the hospital may submit in writing, with a copy to HCFA, 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

HCFA 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 HCFA.

(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 HCFA 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 HCFA 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 HCFA Ruling.

(e) *Communication procedures.* All communications between HCFA 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 HCFA 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 HCFA staff and the Administrator concerning MGCRB decisions reviewed by the Administrator under paragraphs (b) or (c) of this section, HCFA 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 HCFA—

(i) Not later than 90 days following receipt of the party's request for review; 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 HCFA.

(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]

§ 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 itselt.

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.* HCFA 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 HCFA within 60 days. Within 90 days, HCFA 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 HCFA 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, HCFA 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 § 412.63.

(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.* For cost reporting periods beginning on or after October 1, 2001, the capital payment amount is based solely on the Federal rate determined under paragraphs (a) and (b) of § 412.308 and updated under paragraph (c) of § 412.308.

(d) *Interim payments.* Interim payments are made to the hospital as provided in § 412.116.

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.* HCFA 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) HCFA 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).

(c) *The Federal rate.* HCFA determines the Federal rate each year by adjusting the standard Federal rate by the following factors.

(1) *Update factor.* After FY 1992, HCFA 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. HCFA 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.* HCFA 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.* HCFA 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, HCFA adjusts the updated standard Federal rate by a budget neutrality factor determined under § 412.352.

(ii) HCFA 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]

§ 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 X DRG weight X Geographic adjustment factor X Large urban add-on X (1 + Capital disproportionate share adjustment factor + capital indirect medical education adjustment factor) X (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.

(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.

§ 412.316 Geographic adjustment factors.

(a) *Local cost variation.* HCFA 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.* HCFA provides an additional payment to a hospital located, for purposes of receiving payment under § 412.63(a), in a large urban area equal to 3.0 percent of what would otherwise be payable to the hospital based on the Federal rate.

(c) *Cost-of-living adjustment.* HCFA provides an additional payment to a hospital located in Alaska and Hawaii equal to [.3152 X (the cost-of-living adjustment factor used to determine payments under § 412.115 – 1)] percent.

§ 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, for purposes of receiving payment under § 412.63(a), 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).

(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]

§ 412.322 Indirect medical education adjustment factor.

(a) *Basic data.* HCFA determines the following for each hospital:

(1) The hospital's number of full-time equivalent residents as determined under § 412.105(g).

(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.

(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].

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, HCFA uses the base year MEDPAR data received as of June 30, 1991 to develop an adjustment to discharges to account for transfers. HCFA 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, HCFA 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, HCFA 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 HCFA 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, HCFA 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, HCFA 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. HCFA 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 HCFA, 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) 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).

(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]

§ 412.331 Determining hospital-specific rates in cases of hospital merger, consolidation, or dissolution.

(a) *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, 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.

(b) *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]

§ 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) HCFA 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) HCFA will issue the minimum payment levels for each class of hospital in determining the additional exception payment in the annual notice of capital prospective payment rates, published in accordance with § 412.8(b).

(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 HCFA Regional Office by the later of October 1, 1992 or 180 days after the extraordinary circumstance causing the unanticipated expenditures for a determination by HCFA 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.* The minimum payment level for qualifying hospitals will be 70 percent.

(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.

(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]

§ 412.352 Budget neutrality adjustment.

For FY 1992 through FY 1995, HCFA 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 HCFA 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.

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:

(a) 75 percent of a 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

(b) 25 percent of the Federal rate, as determined under § 412.308.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

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413.321 Simplified cost reports for SNFs.

AUTHORITY: Secs. 1102, 1861(v)(1)(A), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(v)(1)(A), and 1395hh).

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) 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.

(D) Section 1833(n) of the Act provides for payment of a blended amount for outpatient hospital diagnostic procedures such as radiology.

(E) Section 1834(c)(1)(C) of the Act establishes the method for determining Medicare payment for screening mammograms performed by hospitals.

(F) Section 1834(g) of the Act provides for payment for rural primary care hospital (RPCH) outpatient services on the basis of prospectively determined amounts.

(G) Section 1881 of the Act authorizes payment for services furnished to ESRD patients.

(H) Section 1883 of the Act provides for payment for post-hospital SNF care furnished by a rural hospital that has swing-bed approval.

(I) Sections 1886(a) and (b) of the Act impose a ceiling on the rate of increase in hospital inpatient costs.

(J) 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 rural primary care hospitals (RPCHs);

(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.

(viii) Community mental health centers (CMHCs) but only for purposes of furnishing partial hospitalization services.

(3) *Applicability.* The payment principles and related policies set forth in this part are binding on HCFA 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 (f) 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, psychiatric, rehabilitation and long-term hospitals (as well as separate psychiatric and rehabilitation units (distinct parts) of short-term general hospitals), which are excluded from the prospective payment system under subpart B of part 412 of this chapter, and to 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.

(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 HCFA. 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) *Prospectively determined payment rates for low Medicare volume SNFs.* Rules governing requests by SNFs for prospectively determined payment rates under section 1888(d) of the Act are set forth in subpart I of this part.

[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]

§ 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) Grants, gifts, and income from endowments will not be deducted from operating costs unless they are designated by the donor for the payment of specific operating costs.

(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]

§ 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—

Fair compensation means, for the purpose of providers that meet the nominal charge provisions in paragraph (f) of this section, the reasonable cost of

covered services furnished to beneficiaries.

New provider means a provider that has operated as the type of facility for which it has been approved for participation in the Medicare program (for example, as a SNF or an HHA) under present and previous ownership for less than three full years.

Provider with a significant portion of low-income patients means a nonpublic provider whose charges are 60 percent or less of the reasonable cost represented by the charges, and that demonstrates, as required under paragraph (c)(1)(iii) of this section, that its charges are less than costs because its customary practice is to charge patients based on their ability to pay.

Public provider means a provider operated by a Federal, State, county, city, or other local government agency or instrumentality.

(b) *Application of the principle of lesser of costs or charges*—(1) *General rule.* Except as provided in paragraph (c) of this section, effective with cost reporting periods beginning on or after January 1, 1974, hospitals, SNFs, HHAs, OPTs, and CMHCs but only for purposes of providing partial hospitalization services, are paid the lesser of the reasonable cost (as described in paragaraph (d) of this section) of covered services furnished to beneficiaries or the customary charges (as defined in paragraph (e) of this section) made by the provider for the same services. The carryover of unreimbursed reasonable costs from previous cost reporting periods is recognized, in accordance with the provisions of paragraph (h) of this section.

(2) *Example.* A provider's reasonable cost for covered services furnished to Medicare beneficiaries during a cost reporting period is $125,000. The customary charges to those beneficiaries for these services is $110,000. The provider is to be reimbursed $110,000 less deductible and coinsurance amounts that the beneficiaries are charged.

(c) *Providers and services not subject to the principle*—(1) *Providers*—(i) *CORFs.* Payment to CORFs is based on the reasonable cost of the services.

(ii) *Public providers.* Public providers furnishing services free of charge or at a nominal charge (as specified in paragraph (f) of this section) are paid fair compensation for services furnished to beneficiaries.

(iii) *Providers furnishing services to a significant portion of low-income patients.* Effective with cost reporting periods beginning on or after October 1, 1984, a provider furnishing services at a nominal charge (as specified in paragraph (f) of this section) is paid fair compensation, upon request, for services furnished to beneficiaries if the provider 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 based on their ability to pay.

(2) *Services*—(i) *Part A inpatient hospital services.* The lesser of costs or charges principle does not apply to Part A inpatient hospital services subject to—

(A) The rate-of-increase limits under § 413.40, effective with cost reporting periods beginning on or after October 1, 1982; or

(B) The prospective payment system under Part 412 of this chapter, effective with cost reporting periods beginning on or after October 1, 1983.

(ii) *Special rule for facility services related to ambulatory surgical procedures performed in outpatient hospital departments.* Effective for hospitals with cost reporting periods beginning on or after October 1, 1987, reasonable costs and customary charges for those services relating to ambulatory surgical procedures that are subject to the payment methodology described in § 413.118 are aggregated and treated separately from all other hospital costs and charges incurred during the cost reporting period.

(iii) *Durable medical equipment furnished by HHAs*—(A) *General.* Except as provided in paragraph (c)(2)(iii)(B) of this section, for durable medical equipment furnished by an HHA as a home health service on or after July 18, 1984, the HHA is paid the lesser of the reasonable cost of the equipment or the customary charges (less a 20 percent coinsurance as provided in section 1866(a)(2)(A)(ii) of the Act), not to exceed 80 percent of the reasonable cost of the equipment. The lesser of cost or charges determination for durable

medical equipment is made separately from all other items or services furnished in an HHA regardless of whether the equipment is furnished under Part A or Part B.

(B) *HHAs meeting the nominal charge provisions.* A public HHA, or an HHA that demonstrates that a significant portion of its patients are low-income patients under the nominal charge provisions, as provided in paragraph (f)(2) of this section, are paid 80 percent of fair compensation for durable medical equipment furnished as a home health service on or after July 18, 1984.

(iv) *Rural Primary Care Hospital (RPCH) services.* The lesser of costs or charges principle does not apply in determining payment for inpatient services furnished by a RPCH under § 413.70(a) or outpatient RPCH services that are paid under the all-inclusive rate method described in § 413.70(b)(3).

(3) *Hospital outpatient radiology services.* The reasonable costs and customary charges for hospital outpatient radiology services furnished on or after October 1, 1988, that are subject to the payment method described in § 413.122, are aggregated and treated separately from all other hospital costs and charges incurred during the cost reporting period.

(4) *Other diagnostic procedures performed by a hospital on an outpatient basis.* The reasonable costs and customary charges for other diagnostic procedures identified by HCFA, that are performed on an outpatient basis by a hospital on or after October 1, 1989, and that are subject to the payment method described in § 413.122, are aggregated and treated separately from all other hospital costs or charges incurred during the cost reporting period.

(d) *Exclusions from reasonable cost.* For purposes of comparison with customary charges under this section, reasonable cost does not include—

(1) Payments made to a provider as reimbursement for bad debts arising from noncollection of Medicare deductible and coinsurance amounts (§ 413.80);

(2) Amounts that represent the recovery of excess depreciation resulting from termination in the Medicare program or a decrease in Medicare utilization (§ 413.134(d)(3)) applicable to prior cost reporting periods;

(3) Amounts that result from a disposition of depreciable assets (§ 413.134(f)), applicable to prior cost reporting periods;

(4) Payments to funds for the donated services of teaching physicians (§ 413.85); and

(5) Graduate medical education costs for cost reporting periods beginning on or after July 1, 1985.

(e) *Customary charges*—(1) *General.* As used in this paragraph (e), customary charges means the charges for services, as defined in § 413.53(b), furnished to beneficiaries. These charges must be recorded on all bills submitted for program reimbursement.

(2) *Special situations in which customary charges are reduced.* 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 and the provider—

(i) Did not actually impose charges in the case of most patients liable for payment for its services on a charge basis; or

(ii) Failed to make a reasonable effort to collect those charges.

(f) *Nominal charges*—(1) *Cost reporting periods beginning before October 1, 1984.* Except for durable medical equipment furnished by HHAs as provided in paragraph (c)(2)(iii) of this section, if a public provider's total charges, for cost reporting periods beginning before October 1, 1984, are less than one-half of the reasonable cost of services or items represented by these charges, then the provider is reimbursed fair compensation.

(2) *Cost reporting periods beginning on or after October 1, 1984.* For cost reporting periods beginning on or after October 1, 1984, the following provisions apply in determining nominal charges:

(i) *Reimbursement of fair compensation.* Except for the limitations on reimbursement for durable medical equipment furnished by HHAs as provided in paragraph (c)(2)(iii) of this section, public providers, and providers with a significant portion of low-income patients that request payment under this

paragraph are reimbursed fair compensation if total charges are 60 percent or less of the reasonable cost of services or items represented by these charges.

(ii) *Separate determination of nominal charges.* Except as provided in paragraph (f)(2)(iii) of this section, the determination of nominal charges, which is based on charges actually billed to charge-paying, non-Medicare patients, is made separately with respect to inpatient and outpatient services (other than clinical diagnostic laboratory tests that are paid under section 1833(h) of the Act).

(iii) *Determination of nominal charges in special situations.* (A) For providers that have a sliding scale or discounted schedule of charges based on patients' ability to pay, the determination of nominal charges is based on charges billed to all charge-paying patients. This determination is made using the ratio of sliding scale or discounted charges to the provider's full customary charges. For determining nominal charges, the ratio is applied to the provider's Medicare charges to equate those charges to customary charges.

(B) For HHAs, the determination of nominal charges for all items and services other than durable medical equipment is made on an aggregate basis. The nominal charge determination for durable medical equipment is made separately from other items or services furnished by HHAs.

(C) For cost reporting periods beginning on or after July 1, 1985, graduate medical education payments (or a provider's graduate medical education reasonable costs if supported by appropriate data) are included in reasonable costs when making the nominal charge determination.

(g) *The aggregation method*—(1) *Cost reporting periods beginning before October 1, 1984—Application.* In comparing costs and charges under the lesser of costs or charges principle for cost reporting periods beginning before October 1, 1984, the reasonable cost for items and services and the customary charges for those same items and services are to be aggregated (that is, totalled and compared) without regard to whether the services are reimbursable under Part A or Part B of Medicare. This aggregation method is to be applied after the provider's charges and costs have been adjusted to exclude the amounts described in paragraph (d) of this section and to exclude—

(i) Any amounts attributable to physician services not reimbursable to the provider on a reasonable cost basis as described in §§ 415.55 through 415.70 of this chapter; and

(ii) All costs and charges for noncovered provider services.

(2) *Cost reporting periods beginning on or after October 1, 1984.* Effective with cost reporting periods beginning on or after October 1, 1984, the aggregation method used for computing the lesser of costs or charges, as set forth in paragraph (g)(1) of this section, may not be used. For covered items and services furnished during these periods, total reasonable cost of covered items and services is compared with total customary charges for those items and services, separately for Part A and for Part B.

(h) *Accumulation of unreimbursed costs and carryover to subsequent periods*—(1) *General rule.* A provider whose charges are lower than its reasonable cost for those services in any cost reporting period beginning on or after January 1, 1974 but before April 28, 1988, may carry forward costs that are unreimbursed under paragraph (b) of this section for the two succeeding cost reporting periods. However, no recovery may be made in any period in which costs are unreimbursed because a provider's costs exceed the limitations on reimbursable costs (§ 413.30) or the ceiling on the rate of hospital cost increases (§ 413.40).

(2) *Reimbursement as a result of carryover.* The provider is reimbursed for the costs that are carried forward to a succeeding cost reporting period—

(i) If total charges for services provided in that subsequent period exceed the total reasonable cost of the services; and

(ii) To the extent that accumulation of the costs being carried forward and the costs for the services provided in that subsequent period do not exceed the customary charges for those services.

(3) *Two succeeding periods less than 24 months.* If the two succeeding cost reporting periods are less than 24 full calendar months, the provider may carry forward the unreimbursed costs for one additional cost reporting period.

(4) *Example.* In the cost reporting period ending September 30, 1982, a provider's reasonable costs were $100,000. The provider's customary charges for those services were $90,000. The provider is reimbursed $90,000 less any deductible and coinsurance amounts but is permitted to carry forward the unreimbursed reasonable costs of $10,000 for the next two succeeding cost reporting periods. If, in the cost reporting period ending September 30, 1983, customary charges to beneficiaries exceeded the reasonable costs for those services by $10,000 or more, and the provider had no costs unreimbursed under § 413.30 or § 413.40, the provider would recover the entire $10,000 previously not reimbursed. If, however, beneficiary charges for that cost reporting period exceeded costs by only $8,000, this amount ($8,000) would be added to the provider's reimbursable costs for this period. The balance of the unreimbursed amount ($2,000) would be carried forward to the next cost reporting period.

(5) *New providers.* (i) *General rule.* A new provider whose cost reporting period begins before April 28, 1988, may carry forward costs that are unreimbursed from previous periods, as described in paragraph (b) of this section, during a provider's base period. The base period includes any cost reporting period beginning on or after January 1, 1974, and ending on or before the last day of its third year of operation. The unreimbursed costs may be carried forward for the five succeeding cost reporting periods. However, no recovery may be made in any period in which costs are unreimbursed because a provider's costs exceed the limitations on reimbursable costs (§ 413.30) or the ceiling on the rate of hospital cost increases (§ 413.40).

(ii) *Reimbursement as a result of carryover.* The new provider is reimbursed for the costs that are carried forward to a succeeding cost reporting period—

(A) If total charges for the services provided in that subsequent period exceed the total reasonable cost of the services; and

(B) To the extent that accumulation of the costs being carried forward and the costs for the services provided in that subsequent period do not exceed the customary charges for those services.

(iii) *Five succeeding periods less than 60 months.* If the five succeeding cost reporting periods are less than 60 full calendar months, the provider may carry forward the unreimbursed costs for one additional cost reporting period.

(iv) *Example.* A provider begins its operations on March 5, 1972. However, it begins to participate in the Medicare program as of January 1, 1973, and reports on a calendar year basis. Because the provider would be subject to the lesser of cost or charges principle for its cost reporting period beginning with January 1, 1974, it would be permitted to accumulate any unreimbursed costs (excess of costs over its charges) incurred during this reporting period. Therefore, because this cost reporting period ends before the end of the third year of operation, its carryover period would be the succeeding five cost reporting periods ending with December 31, 1979. If this provider had begun its operation on July 1, 1973, and become a participating provider as of the same date (with a fiscal year ending June 30), it would have been able to accumulate any unreimbursed costs for the two cost reporting periods ending June 30, 1975, and June 30, 1976. Its carryover period would then be the five cost reporting periods ending no later than June 30, 1981, in the case of costs unreimbursed in either of the reporting periods ending June 30, 1975, or June 30, 1976.

[53 FR 10085, Mar. 29, 1988; 53 FR 12641, Apr. 15, 1988; 54 FR 40315, Sept. 29, 1989; 56 FR 8842, Mar. 1, 1991; 58 FR 30670, May 26, 1993; 59 FR 6578, Feb. 11, 1994; 60 FR 63189, Dec. 8, 1995]

§ 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, HCFA), 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 § 405.371(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 § 405.371(a) of this chapter, to submit a statement (including any pertinent evidence) as to why the suspension must not be put into effect.

§ 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 HCFA.

(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 HCFA 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.

(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 HCFA.

(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) Effective for cost reporting periods beginning on or after October 1, 1989, a hospital is required to submit its cost reports in a standardized electronic format. The hospital's electronic program must be capable of producing the HCFA standardized output file in a form that can be read by intermediary's automated system. This electronic file, which must contain the input data required to complete the cost report and the data required to pass specified edits, is forwarded to the fiscal intermediary for processing through its system.

(ii) The fiscal intermediary stores the hospital'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, final settlement, etc). The hospital'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 rejects the cost report and returns it to the hospital 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.

(iii) Effective for cost reporting periods ending on or after September 30, 1994, a hospital 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. The following statement must immediately precede the dated signature of the hospital'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.

(iv) A hospital may request a delay or waiver of the electronic submission requirement in paragraph (f)(4)(i) of this section if this requirement would cause a financial hardship. The hospital must submit a written request for delay or waiver with necessary supporting documentation to its intermediary at least 120 days prior to the end of its cost reporting period. The intermediary reviews the request and forwards it with a recommendation for approval or denial, to HCFA central office within 30 days of receipt of the request. HCFA 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 HCFA).

(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 HCFA.

(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 HCFA 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]

Subpart C—Limits on Cost Reimbursement

§ 413.30 Limitations on reimbursable costs.

(a) *Introduction.* (1) *Scope.* This section implements section 1861(v)(1)(A) of the Act, by setting forth the general rules under which HCFA may establish limits on provider costs recognized as reasonable in determining Medicare program payments, and sections 1861(v)(7)(B) and 1886(a) of the Act, by setting forth the general rules under which HCFA may establish limits on the operating costs of inpatient hospital services that are recognized as reasonable in determining Medicare program payments. (For cost reporting periods beginning on or after October 1, 1983, the operating costs incurred in furnishing inpatient hospital services are not subject to the provisions of this section.) This section also sets forth rules governing exemptions, exceptions, and adjustments to limits established under this section that HCFA may make as appropriate in consideration of special needs or situations of particular providers.

(2) *General principle.* Reimbursable provider costs may not exceed the costs estimated by HCFA to be necessary for the efficient delivery of needed health services. HCFA may establish estimated cost limits for direct or indirect overall costs or for costs of specific items or services or groups of items or services. These limits will be imposed prospectively and may be calculated 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, HCFA may classify providers by type of provider (for example, hospitals, SNFs, and HHAs) and by other factors HCFA finds appropriate and practical, including—

(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; or

(v) Type and mix of patients treated.

(2) Estimates of the costs necessary for efficient delivery of health services may be based on cost reports or other data providing indicators of current costs. Current and past period data will be adjusted to arrive at estimated costs for the prospective periods to which limits are being applied.

(3) Prior to the beginning of a cost period to which revised limits will be applied, HCFA will publish a notice in the FEDERAL REGISTER, establishing cost limits and explaining the basis on which they were calculated.

(4) In establishing limits under paragraph (b)(1) of this section, HCFA may find it inappropriate to apply particular limits to a class of providers due to the characteristics of the provider class, the data on which those limits are based, or the method by which the limits are determined. In such cases, HCFA may exclude that class of providers from the limits, explaining the basis of the exclusion in the notice setting forth the limits for the appropriate cost reporting periods.

(c) *Provider requests regarding applicability of cost limits.* A provider may request a reclassification, exception, or exemption from the cost limits imposed under this section. In addition, a hospital may request an adjustment to the cost limits imposed under this section. The provider's request must be made to its fiscal intermediary within 180 days of the date on the intermediary's notice of program reimbursement. The intermediary makes a recommendation on the provider's request to HCFA, which makes the decision. HCFA responds to the request within 180 days from the date HCFA receives the request from the intermediary. The intermediary notifies the provider of HCFA's decision. The time required for HCFA to review the request is considered good cause for the granting of an extension of the time limit to apply for a Board review, as specified in § 405.1841 of this chapter. HCFA's decision is subject to review under subpart R of part 405 of this chapter.

(d) *Reclassification.* A provider may obtain a reclassification if it can show that its classification is at variance with the criteria specified in promulgating the limits.

(e) *Exemptions.* Exemptions from the limits imposed under this section may be granted to a new provider. A new provider is a provider of inpatient services that has operated as the type of provider (or the equivalent) for which it is certified for Medicare, under present and previous ownership, for less than three full years. An exemption granted under this paragraph expires at the end of the provider's first cost reporting period beginning at least two years after the provider accepts its first patient.

(f) *Exceptions.* Limits established under this section may be adjusted upward for a provider under the circumstances specified in paragraphs (f)(1) through (f)(5) of this section. An adjustment is made only to the extent the costs are reasonable, attributable to the circumstances specified, separately identified by the provider, and verified by the intermediary.

(1) *Atypical services.* The provider can show that the—

(i) Actual cost of items or services furnished by a provider exceeds the applicable limit because such items or services are atypical in nature and scope, compared to the items or services generally furnished by providers similarly classified; and

(ii) Atypical items or 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 provider 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 similar unusual occurrences with substantial cost effects.

(3) *Providers in areas with fluctuating populations.* (i) The provider is located in an area (for example, a resort area) that has a population that varies significantly during the year;

(ii) The appropriate health planning agency has determined that the area does not have a surplus of beds and similar services and has certified that the beds and services made available by the provider are necessary; and

(iii) The provider meets occupancy standards established by the Secretary.

(4) *Medical and paramedical education.* The provider can demonstrate that, if compared to other providers in its group, it incurs increased costs for items or 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 provider has a percentage of labor costs that varies more than 10 percent from that included in the promulgation of the limits.

(g) *Operational review of providers receiving an exception.* Any provider that applies for an exception to the limits established under paragraph (f) of this section must agree to an operational review at the discretion of HCFA. The findings from any such review may be the basis for recommendations for improvements in the efficiency and economy of the provider's operations. If such recommendations are made, any future exceptions shall be contingent

on the provider's implementation of these recommendations.

(h) *Adjustments.* For cost reporting periods beginning on or after October 1, 1982 and before October 1, 1983, HCFA may adjust the amount of a hospital's inpatient operating costs to take into account factors that could result in a significant distortion in the operating costs of inpatient hospital services. Such factors could include a decrease in the inpatient services that a hospital provides that are customarily provided directly by similar hospitals, or the manipulation of discharges to increase reimbursement. A decrease in inpatient services could result from changes that include, but are not limited to, such actions as closing a special care unit or changing the arrangements under which such services may be furnished, such as leasing a department.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 53 FR 38533, Sept. 30, 1988; 60 FR 45849, Sept. 1, 1995]

§ 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) HCFA 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 HCFA. 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 HCFA 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.

(ii) For cost reporting periods beginning on or after October 1, 1983, this section applies to hospitals excluded from the prospective payment system in accordance with § 412.23 of this chapter, and psychiatric and rehabilitation units excluded from the prospective payment system in accordance with §§ 412.25 through 412.30 of this chapter.

(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.

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 HCFA'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 §§ 413.85 and 413.86, 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 a unit or vice versa) the base period is the first cost reporting period of at least 12 months effective with the revised Medicare certification classification.

(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.* Net inpatient operating costs include certain preadmission services furnished by the hospital or by an entity wholly owned or operated by the hospital (that is, any entity for which the hospital itself is the sole owner or operator) to the patient on the calendar day immediately preceding the date of the patient's admission to the hospital. A hospital is considered the sole operator of an entity if the hospital has exclusive responsibility for conducting or overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity. The specific preadmission services (other than ambulance services) included in the net inpatient hospital operating costs are the following:

(i) Diagnostic services (including clinical diagnostic laboratory tests) furnished on or after January 1, 1991.

(ii) Other services related to the admission furnished on or after October 1, 1991. Other services related to the admission means services (other than diagnostic services) that are furnished in connection with the principal diagnosis that requires the beneficiary to be admitted as an inpatient.

(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 and following.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1998, is the percentage increase projected by the hospital market basket index.

(4) *Target amount.* The intermediary will establish a target amount for each hospital. The target amount for each cost reporting period is determined as follows:

(i) 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) 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.

(5) *Applicable update factor.* (i) The applicable update factor is derived from the prospectively determined rate-of-increase percentage published by HCFA. 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.* 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—

(i) Net inpatient operating costs plus 50 percent of the difference between inpatient operating costs and the ceiling; or

(ii) Net inpatient operating costs plus 5 percent of the ceiling.

(3) *Net inpatient operating costs are greater than the ceiling.* For cost reporting periods beginning on or after October 1, 1991, if a hospital's allowable net inpatient operating costs exceed the hospital's ceiling (or the adjusted ceiling, if applicable), payment will be based on the lower of the—

(i) Ceiling (or the adjusted ceiling, if applicable) plus 50 percent of the allowable net inpatient operating costs in excess of the ceiling (or the adjusted ceiling, if applicable); or

(ii) One hundred-ten percent of the ceiling (or the adjusted ceiling, if applicable).

(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 HCFA has authorized the intermediary to make the decision, the intermediary makes a recommendation on the hospital's request to HCFA, which makes the decision. HCFA 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 HCFA 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) *Exemptions.* (1) *New hospitals.* (i) A new 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. 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 HCFA granted it approval to participate in the Medicare program, under present or previous ownership (or both), for less than two full years; and

(B) Has provided the type of hospital inpatient services for which HCFA granted it approval to participate in the Medicare program, for less than two years.

(ii) 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.

(iii) A decision issued under paragraph (f)(1) 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 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 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).

(2) *New units.* A newly established unit that is excluded from the prospective payment 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)(1) 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) of this section.

(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 rule.* HCFA may adjust 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 below. When an adjustment is requested by the hospital, HCFA 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. HCFA may grant an adjustment requested by the hospital only if a hospital's operating costs exceed the rate-of-increase ceiling imposed under this section. The amount of payment made to a hospital after an adjustment under paragraph (g) of this section may not exceed the difference between the hospital's operating costs and the payment previously allowed.

(2) *Extraordinary circumstances.* HCFA 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.* HCFA 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, HCFA 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.* HCFA 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, 1998, the payment reductions under paragraph (c)(2)(v) 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, HCFA 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, HCFA 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, HCFA 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.

[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]

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, 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) Do not include private rooms furnished for SNF-type and ICF-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 method.* (i) The carve 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, the total costs attributable to the SNF-type and ICF-type services furnished to all classes of patients are subtracted from total general routine inpatient service costs before computing the average cost per diem for general routine hospital care.

(ii) The cost per diem attributable to the routine SNF-type services furnished by a swing-bed hospital is based on the reasonable cost per diem for services determined in accordance with § 413.114.

(iii) The cost per diem attributable to the routine ICF services furnished by the swing-bed hospital is determined as follows:

(A) If the hospital is located in a State that provides for ICF services under Medicaid, the cost per diem for ICF services furnished by a swing-bed hospital in that State is based on the Statewide average rate paid for routine services in ICFs (other than ICFs for the mentally retarded) during the preceding calendar year under the State Medicaid plan. The Statewide average rate will be computed either by the State and furnished to HCFA, or by HCFA directly based on the best available data.

(B) If the hospital is located in a State that does not provide for ICF services under Medicaid or that does not have a Medicaid program, the cost per diem for ICF services will be based on the average ratio of the ICF rate to the SNF rate in those States that provide for both SNF and ICF services under Medicaid. The ratio will be applied to the SNF cost per diem determined under paragraph (a)(2)(ii) of this section.

(iv) The sum of total SNF-type days furnished to all classes of patients multiplied by the SNF cost per diem, and total ICF-type days furnished to all classes of patients multiplied by the appropriate ICF cost per diem, will be subtracted from inpatient general routine service costs. The cost per diem for inpatient general routine hospital care will be based on the remaining general routine service costs.

(v) Costs other than general inpatient routine service costs will be determined in the same manner as specified in the Departmental Method in paragraph (a)(1) of this section.

(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 HCFA (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 costs attributable to SNF-type and ICF-type services 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 SNF-type and ICF-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 and 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.

ICF-type services means routine services furnished by a swing-bed hospital that would constitute intermediate care facility (ICF) services, as defined in § 440.150 of this chapter, if furnished by an ICF. ICF-type services are not covered under the Medicare program.

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 post-operative 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.)

SNF-type services means routine services furnished by a swing-bed hospital that would constitute extended care services if furnished by an SNF. SNF-type services include routine 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).

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 of 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]

§ 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 HCFA. 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 and for both Part A and Part B HHA services.

(2) *Covered services furnished on or after July 1, 1987.* Effective with claims received on or after July 1, 1987, the periodic interim payment (PIP) method is available for the following:

(i) Part A inpatient hospital services furnished in hospitals that are excluded from the prospective payment systems under subpart B 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 HCFA 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.

(iv) Part A and Part B HHA services.

(v) 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.

(vi) 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.

(3) Any participating provider furnishing the services described in paragraph (h)(1) 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.

(iv) The provider has repaid or agrees to repay any outstanding current financing payment in full, such payment to be made before the effective date of its requested conversion from a regular interim payment method to the PIP method.

(4) No conversion to the PIP method may be made with respect to any provider until after that provider has repaid in full its outstanding current financing payment.

(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]

§413.70 Payment for services of an RPCH.

(a) *Payment for inpatient services furnished by an RPCH.* (1) *Initial 12-month period of operation.* Payment for the first 12-month cost reporting period for which the RPCH operates as an RPCH is made on a per diem basis for the reasonable costs of the RPCH for inpatient services. This payment does not include physician and other practitioner services paid on a charge or fee basis, and is subject to the principles of cost reimbursement in this part and in part 405, subpart D of this chapter; however, the principle of the lesser of costs or charges in §413.13 does not apply.

(2) *Subsequent periods.* Payment for a cost reporting period subsequent to the initial 12-month period for which the RPCH operates as an RPCH is made on the basis of adjusting the amount determined in paragraph (a)(1) of this section. The adjustment added to the per diem amount is the market basket percentage increase under section 1886(b)(3)(B)(i) of the Act for the subsequent cost reporting period applicable to hospitals located in rural areas.

(3) *Reduction for grants.* The payment amounts otherwise determined under this paragraph (a) are reduced to the extent necessary to avoid any duplication of any grant payments made under section 1820(a)(2) of the Act or under section 4005(e) of the Omnibus Budget Reconciliation Act of 1987, Grant Program for Rural Health Care Transition, to cover the provision of inpatient RPCH services.

(b) *Payment for outpatient services furnished by an RPCH.* (1) *General.* An RPCH may elect either the method in paragraph (b)(2) of this section or the method in paragraph (b)(3) of this section for payment for outpatient services. The method of payment elected by the RPCH must be made in writing on an annual basis prior to the beginning of the affected cost reporting period.

(2) *Cost-based RPCH payment plus professional services method.* (i) *RPCH services.* Payment under this method for outpatient RPCH services is equal to the amounts described in section 1833(a)(2)(B) of the Act (which describes amounts paid for hospital outpatient services) and subject to the applicable

principles of cost reimbursement in this part and in part 405, subpart D of this chapter, except for the principle of the lesser of costs or charges in § 413.13. This payment is subject to applicable part B deductible and coinsurance amounts. This payment does not include payment for physician services or other professional services paid on a charge or other fee basis.

(ii) *Professional services.* Payment for professional medical services furnished in an RPCH is made on a charge or other fee basis under the provisions of this chapter that would apply to payment for the services if they had not been furnished in an RPCH. For purposes of RPCH payment, professional medical services are defined as those services provided by a physician or other professional (for example, a physician assistant, an anesthetist, and a nurse practitioner) that could be billed separately to a carrier under Medicare.

(3) *All-inclusive rate method.* (i) If the RPCH elects payment under this method, a combined payment including both RPCH facility services and professional medical services is made at an all-inclusive rate per visit. This rate is subject to applicable part B deductible and coinsurance amounts, as described in § 410.3(b) of this chapter. The all-inclusive rate is an average rate based on the reasonable costs of RPCH facility services and professional services, as defined in the principles of cost reimbursement, divided by the number of outpatient RPCH visits. In determining reasonable costs, the principle of the lesser of costs or charges in § 413.13 does not apply.

(ii) All health professionals must have a compensation arrangement with the RPCH. The health professionals' actual time is divided among inpatient services, outpatient services, and nonallowable activities such as research; the percentage of actual time applicable to outpatient services is applied to total compensation. The resulting amount is included with the RPCH's outpatient facility costs for determination of the average cost per outpatient RPCH visit. (No breakdown is required for physician professional services versus technical services.)

(iii) A RPCH outpatient visit represents a face-to-face encounter between the patient and a health professional during which the RPCH outpatient services are furnished. Encounters with more than one health professional and multiple encounters with the same health professionals which take place on the same day constitute a single visit, except for cases in which subsequent encounters occur on the same day for an injury or illness requiring additional diagnosis or treatment different from the injury or illness associated with the initial encounter. These subsequent encounters are counted as separate visits.

(iv) Final reimbursement to the RPCH is based on a year-end cost report, as required under § 413.20(b), that provides for the average per visit amount methodology.

[58 FR 30670, May 26, 1993, as amended at 60 FR 45850, Sept. 1, 1995]

§ 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

§ 413.80 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) *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]

§ 413.85 Cost of educational activities.

(a) *Payment*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, a provider's allowable cost may include its net cost of approved educational activities, as calculated under paragraph (g) of this section. The net cost is subject to apportionment based on Medicare utilization as described in § 413.50.

(2) *Exception.* For cost reporting periods beginning on or after July 1, 1985, payment to hospitals and hospital-based providers for approved residency programs in medicine, osteopathy, dentistry, and podiatry is determined as provided in § 413.86.

(b) *Definition—Approved educational activities.* Approved educational activities means formally organized or planned programs of study usually engaged in by providers in order to enhance the quality of patient care in an institution. These activities must be licensed if required by State law. If licensing is not required, the institution must receive approval from the recognized national professional organization for the particular activity.

(c) *Educational activities.* Many providers engage in educational activities including training programs for nurses, medical students, interns and residents, and various paramedical specialties. These programs contribute to the quality of patient care within an institution and are necessary to meet the community's needs for medical and paramedical personnel. It is recognized that the costs of such educational activities should be borne by the community. However, many communities have not assumed responsibility for financing these programs and it is necessary that support be provided by those purchasing health care. Until communities undertake to bear these costs, the program will participate appropriately in the support of these activities. Although the intent of the program is to share in the support of educational activities customarily or traditionally carried on by providers in conjunction with their operations, it is not intended that this program should participate in increased costs resulting from redistribution of costs from educational institutions or units to patient care institutions or units.

(d) *Activities not within the scope of this principle.* The costs of the following activities are not within the scope of this principle but are recognized as normal operating costs and are reimbursed in accordance with applicable principles—

(1) Orientation and on-the-job training;

(2) Part-time education for bona fide employees at properly accredited academic or technical institutions (including other providers) devoted to undergraduate or graduate work;

(3) Costs, including associated travel expense, or sending employees to educational seminars and workshops that increase the quality of medical care or operating efficiency of the provider;

(4) Maintenance of a medical library;

(5) Training of a patient or patient's family in the use of medical appliances;

(6) Clinical training of students not enrolled in an approved education program operated by the provider; and

(7) Other activities that do not involve the actual operation of an approved education program including the costs of interns and residents in anesthesiology who are employed to replace anesthetists.

(e) *Approved programs.* Recognized professional and paramedical educational training programs now being conducted by provider institutions, and their approving bodies, include the following:

(1) Cyto-technology.	Committee on Allied Health, Education, and Accreditation in collaboration with the Board of Schools of Medical Technology, American Society of Clinical Pathologists.

(2) Dietetic internships.	The American Dietetic Association.
(3) Hospital administration residencies.	Accrediting Commission on Education in Health Services Administration.
(4) Inhalation therapy.	Committee on Allied Health, Education, and Accreditation in collaboration with the Board of Schools of Inhalation Therapy.
(5) Medical records.	Committee on Allied Health, Education, and Accreditation in collaboration with the Committee on Education and Registration of the American Association of Medical Records Librarians.
(6) Medical technology.	Committee on Allied Health, Education, and Accreditation in collaboration with the Board of Schools of Medical Technology, American Society of Clinical Pathologists.
(7) Nurse anesthetists.	The American Association of Nurse Anesthetists.
(8) Professional nursing.	Approved by the respective State approving authorities. Reported for the United States by the National League for Nursing.
(9) Practical nursing.	Approved by the respective State approving authorities. Reported for the United States by the National League for Nursing.
(10) Occupational Therapy.	Committee on Allied Health, Education, and Accreditation in collaboration with the Council on Education of the American Occupational Therapy Association.
(11) Pharmacy residencies.	American Society of Hospital Pharmacists.
(12) Physical therapy.	Committee on Allied Health, Education, and Accreditation in collaboration with the American Physical Therapy Association.
(13) X-ray technology.	Committee on Allied Health, Education, and Accreditation in collaboration with the American College of Radiology.

(f) *Other educational programs.* There may also be other educational programs not included in the foregoing in which a provider institution is engaged. Appropriate consideration will be given by the intermediary and HCFA to the costs incurred for those activities that come within the purview of the principle when determining the allowable costs for apportionment under the Medicare program.

(g) *Calculating net cost.* Net costs of approved educational activities are determined by deducting, from a provider's total costs of these activities, revenues it receives from tuition. For this purpose, a provider's total costs include trainee stipends, compensation of teachers, and other direct and indirect costs of the activities as determined under the Medicare cost-finding principles in § 413.24.

[51 FR 34793, Sept. 30, 1986, as amended at 54 FR 40315, Sept. 29, 1989]

§ 413.86 Direct graduate medical education payments.

(a) *Statutory basis and scope*—(1) *Basis.* This section implements 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 applies 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, the following definitions apply:

Approved geriatric program means a fellowship program of one or more years in length that is approved by the Accreditation Council for Graduate Medical Education (ACGME) under the ACGME'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 § 415.200(a) 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.

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.

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.

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.

(c) *Payment for graduate medical education 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 graduate medical education programs as described in paragraph (d) through (h) of this section.

(d) *Calculating payment for graduate medical education costs.* A hospital's Medicare payment for the costs of an approved residency program is calculated as follows:

(1) *Step one.* The hospital's updated per resident amount (as determined under paragraph (e) of this section) is multipled by the actual number of FTE residents (as determined under paragraph (g) of this section). This result is the aggregate approved amount for the cost reporting period.

(2) *Step two.* The product derived in step one is multipled by the hospital's Medicare patient load.

(3) *Step three.* 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 graduate medical education costs attributable to each part as determined through the Medicare cost report.

(e) *Determining per resident amounts for the base period*—(1) *For the base period.* (i) Except as provided in paragraph (e)(4) of this section, the intermediary determines a base-period per resident amount for each hospital as follows:

(A) Determine the allowable graduate medical education costs for the cost reporting period beginning on or after October 1, 1983 but before October 1, 1984. In determining these costs, graduate medical education 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 graduate medical education costs allocated to distinct-part hospital units and hospital-based providers that participate in Medicare are included.

(B) Divide the costs calculated in paragraph (e)(1)(i)(A) 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 (e)(1)(i)(A) of this section) for its cost reporting period beginning on or after October 1, 1983 but before October 1, 1984.

(ii) In determining the base-period per resident amount under paragraph (e)(1)(i) of this section, the intermediary—

(A) Verifies the hospital's base-period graduate medical education costs and the hospital's average number of FTE residents;

(B) Excludes from the base-period graduate medical education costs any nonallowable or misclassified costs, including those previously allowed under § 412.113(b)(3) of this chapter; and

(C) Upon a hospital's request, includes graduate medical education 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 graduate medical education 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 paragraph (j)(2) of this section.

(iii) 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.

(iv) If the intermediary modifies a hospital's base-period graduate medical education costs as described in paragraph (e)(1)(ii)(B) of this section, the hospital may request an adjustment of its prospective payment hospital-specific rate or target amount as described in paragraph (j)(1) of this section.

(v) The intermediary notifies each hospital that either had direct graduate medical education 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.

(2) *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:

(i) 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.

(ii) 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.

(3) *For cost reporting periods beginning on or after July 1, 1986.* For cost reporting periods beginning on or after July 1, 1986, a hospital's base-period per resident amount is adjusted as follows:

(i) Except as provided in paragraph (e)(3)(ii) 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.

(ii) 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.

(4) *Exceptions*—(i) *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 graduate medical education 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 following:

(A) The hospital's actual costs, incurred in connection with the graduate medical education program for the hospital's first cost reporting period in which residents were on duty during the first month of the cost reporting period.

(B) The mean value of per resident amounts of hospitals located in the same geographic wage area, as that term is used in the prospective payment system under part 412 of this chapter, for cost reporting periods beginning in the same fiscal years. If there are fewer than three amounts that can be used to calculate the mean value, the intermediary must contact HCFA Central Office for a determination of the appropriate amount to use.

(ii) *Short or long base-period cost reporting periods.* If a hospital's base-period cost reporting period reflects graduate medical education 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.

(iii) *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 HCFA Central Office to receive a special CPI–U adjustment factor.

(f) *Determining the total number of FTE residents.* (1) Subject to the weighting factors in paragraphs (g) and (h) of this section, the count of FTE residents is determined as follows:

(i) Residents in an approved program working in all areas of the hospital complex may be counted.

(ii) No individual may be counted as more than one FTE. If a resident spends time in more than one hospital or, except as provided in paragraph (f)(1)(iii) of this section, in a nonprovider setting, the resident counts as a 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.

(iii) On or after July 1, 1987, 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:

(A) The resident spends his or her time in patient care activities.

(B) 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.

(2) 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.

(i) The name and social security number of the resident.

(ii) 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.

(iii) The dates the resident is assigned to the hospital and any hospital-based providers.

(iv) The dates the resident is assigned to other hospitals, or other freestanding providers, and any nonprovider setting during the cost reporting period, if any.

(v) The name of the medical, osteopathic, dental, or podiatric school from which the resident graduated and the date of graduation.

(vi) If the resident is an FMG, documentation concerning whether the resident has satisfied the requirements of paragraph (h) of this section.

(vii) The name of the employer paying the resident's salary.

(g) *Determining the weighted number of FTE residents.* Subject to the provisions in paragraph (h) of this section, HCFA 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:

(1) For purposes of this section, an initial residency period is the number of years necessary to satisfy the minimum requirements for certification in a specialty or subspecialty, plus one year. Effective August 10, 1993, residents or fellows in an approved preventive medicine residency or fellowship program may also be counted as a full FTE resident for up to two additional years beyond the initial residency period limitations. Effective July 1, 1995, an initial residency period is defined as the minimum number of years required for board eligibility. An initial residency period may not exceed five years in order to be counted toward determining FTE status except in the case of fellows in an approved geriatric program whose initial residency period may last up to two additional years. For combined residency programs, an initial residency period is defined as the time required for individual certification in the longer of the programs.

(i) For residency programs other than those specified in paragraphs (g)(1)(ii) and (g)(1)(iii) 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 1985–1986 Directory of Residency Training Programs.

(ii) 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 § 415.200(a) of this chapter.

(iii) For residency programs in geriatric medicine approved by the ACGME, as set forth in later editions of the directory specified in paragraph (g)(1)(ii) of this section, these programs are considered approved programs retroactively to the latter of—

(A) The starting date of the program within a hospital; or

(B) The hospital's costs reporting period beginning on or after July 1, 1985.

(iv) 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 paragraph (b) of this section, is counted toward the initial residency period limitation.

(2) If the resident is in an initial residency period, the weighting factor is one.

(3) 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 is .50 thereafter without regard to the hospital's cost reporting period.

(h) *Determination of weighting factors for foreign medical graduates.* (1) The weighting factor for a foreign medical

graduate is determined under the provisions of paragraph (g) of this section if the foreign medical graduate—

(i) Has passed FMGEMS; or

(ii) Before July 1, 1986, received certification from, or passed an examination of, the Educational Committee for Foreign Medical Graduates.

(2) Before July 1, 1986, the weighting factor for a foreign medical graduate is 1.0 times the weight determined under the provisions of paragraph (g) of this section. 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 (h)(1) of this section is .50 times the weight determined under the provisions of paragraph (g) of this section.

(3) On or after July 1, 1987, these foreign medical graduates are not counted in determining the number of FTE residents.

(4) 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 paragraph (g) of this section for the part of the cost reporting period beginning with the month the resident passes the test.

(5) 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 (h)(1) and (h)(4) of this section.

(6) 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 (h)(1) and (h)(4) of this section. On or after July 1, 1993 only the results of steps I and II of the United States Medical Licensing Examination shall be accepted for purposes of making this determination.

(i) *Special rules for States that formerly had a waiver from Medicare reimbursement principles.* (1) 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.

(2) 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.

(3) Per resident amounts are determined for the base period and updated as described in paragraph (e) of this section. For cost reporting periods beginning on or after January 1, 1986, payment is made based on the methodology described in paragraph (d) of this section.

(j) *Adjustment of a hospital's target amount or prospective payment hospital-specific rate*—(1) *Misclassified operating costs*—(i) *General rule.* If a hospital has its base-period graduate medical education costs reduced under paragraph (e)(1) 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.

(ii) *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.

(iii) *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.

(2) *Misclassification of graduate medical education costs*—(i) *General rule.* If costs that should have been classified as graduate medical education costs were treated as operating costs during both the graduate medical education 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 graduate medical education costs in the graduate medical education 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.

(ii) *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.

(iii) *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.

[54 FR 40316, Sept. 29, 1989; 55 FR 290, Jan. 4, 1990; 56 FR 43243, Aug. 30, 1991; 57 FR 39830, Sept. 1, 1992; 58 FR 46343, Sept. 1, 1993; 59 FR 45401, Sept. 1, 1994; 60 FR 63189, Dec. 8, 1995; 61 FR 46225, Aug. 30, 1996]

§ 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 are allowable to the extent that such costs are not met by funds provided for the research. Under this principle, however, studies, analyses, surveys, and related activities to serve the provider's administrative and program needs, are not excluded as allowable costs in the determination of reimbursement under Medicare.

§ 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.* 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 tax is based) is actually made to the employee. For example, no legal obligation exists for a provider-employer to pay FICA taxes until the employee is paid and the specific amount of liability known.

(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]

§ 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 HCFA 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 HCFA. 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, HCFA 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) 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 binding contract.* A provider will be excepted from the provisions of this section if it has a binding contract in writing with a therapist or contracting organization entered into prior to the date guidelines are published. Before the exception may be granted, however, the provider must submit the contract to its intermediary for a determination under this paragraph, subject to review and approval by the Regional Office. Such an exception may be granted for the contract period, but not longer than one year from the date initial guidelines for the particular therapy are published.

(2) *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.

(3) *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).

(4) *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.

§ 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 having a swing-bed approval. Payments to these hospitals for posthospital SNF care furnished in general routine inpatient beds are based on the reasonable cost of posthospital SNF care in accordance with paragraph (c) of this section. Swing-bed hospitals approved after March 31, 1988 with more than 49 beds must meet additional payment requirements as set forth in paragraph (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 HCFA Regional Office makes a determination.

Swing-bed hospital means a hospital or RPCH participating in Medicare that has an approval from HCFA 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) *Principle.* The reasonable cost of posthospital SNF care furnished by a swing-bed hospital is determined as follows:

(1) If a hospital is located in a State participating in Medicaid, the reasonable cost of the routine services is based on the average Statewide rate per patient day paid under the State Medicaid plan for routine services furnished by SNFs in that State during the previous calendar year. The Statewide average rate will be computed either by—

(i) The State and furnished to HCFA; or

(ii) HCFA directly based on the best available data.

(2) If a hospital is located in a State that is not participating in Medicaid, the reasonable cost of the routine services is based on the average reasonable

cost per patient day under Medicare for routine services furnished by SNFs in that State during the previous calendar year. HCFA will determine the average reasonable cost using Medicare cost reports, with adjustments to account for cost reporting periods not covering the calendar year preceding the year for which the rate is to be effective.

(3) 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.* Prior to Medicare payment being 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]

§ 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 HCFA 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.

(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]

§ 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 HCFA, 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.

(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.

[56 FR 8842, Mar. 1, 1991, as amended at 57 FR 36017, Aug. 12, 1992]

§ 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, and rural primary care hospitals, the reasonable costs of outpatient hospital services (other than capital-related costs of such services) are reduced by 5.8 percent for services rendered during portions of cost reporting periods occurring on or after October 1, 1990, and before October 1, 1998.

(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]

§ 413.125 Payment for home health services.

For additional rules on the allowability of certain costs incurred by home health agencies, see §§ 409.46 and 409.49(b) of this chapter.

[59 FR 65497, Dec. 20, 1994]

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 rural primary care 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, through September 30, 1998.

(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]

§ 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.* For depreciable assets acquired after July 31, 1970, and for a hospital or a 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.

(ii) *Hospitals and SNFs only.* (A) For assets acquired on or after July 18, 1984 and not subject to an enforceable agreement entered into before that date, 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 HCFA. If HCFA has not published applicable useful life guidelines, providers must use—

(A) The edition of the American Hospital Association useful life guidelines, as specified in HCFA 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) HCFA 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 HCFA 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 results in a gain or loss, an adjustment is necessary in the provider's allowable cost. 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.* (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) *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) *Limitation on Federal participation for capital expenditures.* The allowance for depreciation is not an allowable cost for certain capital expenditures as described in § 413.161.

(l) *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.

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§ 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 § 405.376 of this chapter); or

(iii) Interest on funds borrowed to repay an overpayment (as described in § 413.64(j) or § 405.376 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 requires that the interest be—

(i) Incurred on a loan made to satisfy a financial need of the provider. Loans that result in excess funds or investments would not be considered necessary;

(ii) Incurred on a loan made for a purpose reasonably related to patient care; and

(iii) Reduced by investment income except if such income is from gifts and grants, whether restricted or unrestricted, and that are held separate and not commingled with other funds. Income from funded depreciation that meets the requirements of § 413.134 or a provider's qualified pension fund is not used to reduce interest expense. Interest received as a result of judicial review by a Federal Court (as described in § 413.64(j)) is not used to reduce interest expense.

(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) *Limitation on Federal participation for capital expenditures.* The allowance for depreciation is not an allowable cost for certain capital expenditures as described in § 413.161.

(f) *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]

§ 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 HCFA 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 of 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

§ 413.170 Payments for covered outpatient maintenance dialysis treatments.

(a) *Basis and purpose.* This section implements section 1881 (b)(2) and (b)(7) of the Act by—

(1) Setting forth the principles and authorities under which HCFA is authorized to establish a prospective reimbursement system for outpatient maintenance dialysis furnished in or under the supervision of an ESRD facility approved under subpart of part 405 of this chapter (referred to as ''facility'' in this section). For purposes of this section and § 413.174, outpatient maintenance dialysis means outpatient dialysis, home dialysis and 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.

(2) Providing for procedures and criteria under which a facility may receive an exception to the prospective payment rates established under this section; and

(3) Establishing procedures and criteria for a facility to appeal its reimbursement under the prospective reimbursement system.

(b) *Principles of prospective reimbursement.* (1) Under prospective reimbursement, payments for outpatient maintenance dialysis are based on rates set prospectively by HCFA.

(2) All approved ESRD facilities must accept the prospective payment rates established by HCFA as payment in full for covered outpatient maintenance dialysis.

(3) HCFA will publish the methodology used to establish rates and changes in payment rates in the FEDERAL REGISTER, as provided in paragraph (i)(2) of this section.

(c) *Prospective rates for hospital-based and independent ESRD facilities.* (1) In accordance with section 1881(b)(7) of the Act, HCFA will establish prospective rates by a methodology that—

(i) Differentiates between hospital-based facilities and independent ESRD facilities;

(ii) Effectively encourages efficient delivery of dialysis services; and

(iii) Provides incentives for increasing the use of home dialysis.

(2) For purposes of rate-setting and reimbursement under this section, HCFA will consider 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 is an initial determination under § 405.1502 of this chapter.

(3) For purposes of rate-setting and reimbursement under this section, HCFA will determine that a facility is hospital-based if the—

(i) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. All authority in management flows from this governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(ii) 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;

(iii) Facility personnel policies and practices conform to those of the hospital;

(iv) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(v) Facility and hospital are financially integrated, as evidenced by the cost report, which must reflect allocation of overhead to the facility through the required step-down methodology.

(4) In determining whether a facility is hospital-based, HCFA will not consider—

(i) An agreement between a facility and a hospital concerning patient referral;

(ii) A shared service arrangement between a facility and a hospital; or

(iii) The physical location of a facility on the premises of a hospital.

(5) If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in § 414.313(c)), the prospective rate (as described in paragraph (c)(1) of this section) paid to that facility will be increased by an add-on amount as described in § 414.313 of this chapter.

(6) *Epoetin (EPO).* (i) 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 (c)(6)(iii) of this section.

(ii) 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 HCFA determines.

(iii) HCFA determines the payment amount in accordance with the following rules:

(A) The amount is prospectively determined.

(B) HCFA publishes annually a FEDERAL REGISTER notice, indicating whether an update in the EPO payment amount is appropriate and requesting public comment.

(C) Any increase in this amount 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.

(D) HCFA sets a single amount to be paid nationwide 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.

(E) The Medicare payment is subject to the Part B deductible and coinsurance.

(7) In addition to the prospective payment described in this section, HCFA makes an additional payment for certain drugs furnished to ESRD patients by a Medicare-approved ESRD facility. HCFA makes this payment directly to the ESRD facility. The facility must accept the allowance determined by HCFA as payment in full. Payment for these drugs is made to the following facilities according to the methodology described:

(i) *Hospital-based.* HCFA makes payment in accordance with the cost-reimbursement rules set forth in this part.

(ii) *Independent.* HCFA 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.

(d) *Amount of payments.* (1) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the treatment, the intermediary will pay the facility 80 percent of its prospective payment rate.

(2) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the treatment, the intermediary will subtract the amount applicable to the deductible from the facility's prospective rate, and will pay the facility 80 percent of the remainder, if any.

(e) *Bad debts.* (1) HCFA will reimburse each facility its allowable Medicare bad debts, up to the facility's costs as determined under Medicare principles, in a single lump sum at the end of the facility's cost reporting period.

(2) A facility must attempt to collect deductible and coinsurance amounts owed by beneficiaries before requesting reimbursement from HCFA for uncollectible amounts. Section 413.80 specifies the efforts facilities must make.

(3) A facility must request reimbursement for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list of all specific noncollections related to covered services.

(f) *Procedures for requesting exceptions to payment rates.* (1) All payments for outpatient maintenance dialysis furnished at or through facilities will be made on the basis of prospective payment rates, without exemption.

(2) If a facility projects on the basis of prior year cost and utilization trends that it will have an allowable cost per treatment higher than its prospective rate set under this section, and if these excess costs are attributable to factors related to one or more of the criteria in paragraph (g) of this section, the facility may request HCFA to approve an exception to that rate and set a higher prospective payment rate.

(3) This higher payment rate will be subject to the rules governing the amount of payment in paragraph (d) of this section.

(4) A facility must request an exception to its payment rate within 180 days after—

(i) It is notified of its prospective payment rate; or

(ii) An extraordinary event with substantial cost effects, as described in paragraph (g)(4) of this section.

(5) The facility is responsible for demonstrating to HCFA's satisfaction that the requirements of this section, including the criteria in paragraph (g) of this section, are met in full. That is, 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. The burden of proof is not on HCFA to show that the criteria are not met, and that the facility's costs are not allowable.

(6) If requesting an exception to its payment rate, a facility must submit to HCFA its most recently completed cost report as required under § 413.174, and whatever statistics, data, and budgetary projections are determined by HCFA to be needed to determine if the exception is approvable. HCFA may audit any cost report or other information submitted. The materials submitted to HCFA must—

(i) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(ii) Show that all of 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;

(iii) Show that the elements of excessive cost are specifically attributable to one or more conditions specified by the criteria set forth in paragraph (g) of this section; and

(iv) Specify the amount of additional reimbursement per treatment the facility believes is required in order to recover its justifiable excess costs.

(7) HCFA will accept an exception request on the date that HCFA concludes that it has received all materials necessary to determine if the exception is approvable.

(8) In determining the facility's payment rate under the exception process, HCFA will exclude all costs that are not allowable under the reasonable cost principles set forth in this part.

(9) Except for exceptions approved under paragraph (g)(4) of this section, a prospective exception payment rate approved by HCFA will apply for the period from the date the exception request was accepted until the earlier of the—

(i) Date the circumstances justifying the exception rate no longer exist; or

(ii) End of the 12-month period during which the announced rate was to apply.

(10) A prospective exception payment rate approved by HCFA under paragraph (g)(4) of this section will apply from the date of the extraordinary event until the end of the 12-month period during which the announced rate was to apply, unless HCFA determines that another date is more appropriate. If HCFA 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 paragraph (f) of this section.

(g) *Criteria for approval of exception requests.* HCFA may approve exceptions

to an ESRD facility's prospective payment rate if the facility demonstrates with convincing objective evidence that its total per treatment costs are reasonable and allowable under § 413.174, and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

(1) *Atypical service intensity (patient mix).* 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. The facility is able to 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. 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) *Isolated essential facility.* The facility is the only supplier of dialysis in its geographical area, its patients cannot obtain dialysis services elsewhere without substantial additional hardship, and its excess costs are justifiable. HCFA will consider local permanent residential population density, typical local commuting distances for medical services, volume of treatments, and dialysis facility usage by area residents other than the applying facility's patients, in determining whether an exception requested on this basis is approvable.

(3) [Reserved]

(4) *Extraordinary circumstances.* The facility incurs excess costs beyond its control due to a fire, earthquake, flood, or other natural disaster. HCFA will not recognize such costs in cases when a facility chose not to maintain adequate insurance protection against such losses (through the purchase of insurance, the maintenance of a self-insurance program, or other equivalent alternative) or chose not to file a claim for losses covered by insurance, or not to utilize its self-insurance program.

(5) *Self-dialysis training costs.* The facility incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for such training sessions.

(6) *Frequency of dialysis.* The facility has a substantial proportion of patients who dialyze less frequently than three times per week. Per treatment payment rates granted under this exception will be no more than the amount that results in weekly reimbursement per patient equal to three times the facility's prospective composite rate, exclusive of any exception amounts.

(h) *Appeals.* (1) *Appeals under section 1878 of the Act.* A facility that disputes the amount of its allowable Medicare bad debts reimbursed by HCFA under paragraph (e) of this section may request a review from the intermediary or the Provider Reimbursement Review Board (PRRB) in accordance with subpart R of part 405 of this chapter.

(2) *Other appeals.* A facility that has requested higher payment per treatment in accordance with paragraph (f) of this section may request a review from the intermediary or the PRRB if HCFA has denied the request in whole or in part. In such a case, the procedure in subpart R of part 405 of this chapter will be followed to the extent that it is applicable. The PRRB, subject to review by the Administrator under § 405.1875 of this chapter, will have the authority to determine whether the HCFA action under review conformed to the provisions of paragraph (f).

(3) *Procedure.* (i) The facility must request a review within 180 days of the date of the decision on which review is sought.

(ii) The facility may not submit to the intermediary or the PRRB any additional information or cost data that were not submitted to HCFA at the

time the facility requested an exception to its prospective payment rate.

(4) *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 (h)(2) of this section—

(i) The amount in controversy per treatment will be determined by subtracting the amount of program payment from the amount the facility requested under paragraph (f) of this section; and

(ii) The total amount in controversy will be calculated by multiplying the amount per treatment by the projected estimated number of treatments for the exception request period (as specified in paragraphs (f) (7) and (8) of this section).

(i) *Notification of changes in rate-setting methodologies and payment rates.* (1) HCFA or the facility's intermediary will notify each facility annually of its payment rate. This notice will include changes in individual facility payment rates resulting from corrections or revisions of particular geographic labor cost adjustment factors.

(2) Changes in payment rates resulting from incorporation of updated cost data, or general revisions of geographic labor cost adjustment factors, will be announced by notice published in the FEDERAL REGISTER without opportunity for prior public comment. Other revisions of the rate-setting methodology will be published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[51 FR 34793, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986, as amended at 54 FR 40319, Sept. 29, 1989; 55 FR 23441, June 8, 1990; 56 FR 43710, Sept. 4, 1991; 56 FR 59624, Nov. 25, 1991; 59 FR 1285, Jan. 10, 1994]

§ 413.174 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 HCFA to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a)(1).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate HCFA-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 services, 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 services (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 413.178, 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.

[51 FR 34793, Sept. 30, 1986, as amended at 59 FR 45402, Sept. 1, 1994; 60 FR 63189, Dec. 8, 1995]

§ 413.178 Reimbursement 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—An OPO or a histocompatibility laboratory is freestanding unless it—

(i) Performs services exclusively for one hospital;

(ii) Is subject to the control of the hospital in regard to the hiring, firing, training and paying of employees; and

(iii) Is 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 for kidneys or other organs the services set forth in § 405.2171(d) of this chapter.

OPO means an organization that meets the definition in § 485.302 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 HCFA 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 HCFA 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 HCFA amounts that have been paid by HCFA 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 the 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.

[53 FR 6548, Mar. 1, 1988; 53 FR 9145, Mar. 21, 1988; 53 FR 18987, May 26, 1988]

§ 413.179 Organ procurement organizations' (OPOs') or transplant centers' costs for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

An OPO's or transplant center'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 § 485.302 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 renal 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.

[54 FR 5623, Feb. 6, 1989]

Subpart I—Prospectively Determined Payment Rates for Skilled Nursing Facilities

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 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.

§ 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, HCFA 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, HCFA 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 HCFA 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, HCFA 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 HCFA–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.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

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Subparts F–H—[Reserved]

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 affecting this part appear at 60 FR 50442, Sept. 29, 1995, and 60 FR 53877, Oct. 18, 1995.

Subpart A—General Provisions

SOURCE: 56 FR 59624, Nov. 25, 1991; 57 FR 42492, Sept. 15, 1992, unless otherwise noted.

§ 414.1 Basis and scope.

This part implements the indicated provisions of the following sections of the Act:

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.

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.

[60 FR 50442, Sept. 29, 1995]

§ 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 HCFA 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.

RVU stands for relative value unit.

[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]

§ 414.4 Fee schedule areas.

(a) *General.* HCFA establishes physician fee schedule areas that generally conform to the geographic localities in existence before January 1, 1992.

(b) *Changes.* HCFA announces proposed changes to fee schedule areas in the FEDERAL REGISTER and provides an opportunity for public comment. After considering public comments, HCFA publishes the final changes in the FEDERAL REGISTER.

[59 FR 63463, Dec. 8, 1994]

§ 414.20 Formula for computing payment amounts.

Under the formula set forth in section 1848(b)(1) of the Act, the fee schedule payment amount for a service defined as a ''physicians' service'' in section 1848(j)(3) of the Act is computed as the product of the following amounts:

(a) The relative value for the service.

(b) The geographic adjustment factor (GAF) for the fee schedule area.

(c) The conversion factor (CF).

§ 414.22 Relative value units (RVUs).

HCFA establishes RVUs for physician work, physician 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.* HCFA 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.

(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.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42493, Sept. 15, 1992; 58 FR 63687, Dec. 2, 1993]

§ 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) HCFA establishes interim RVUs for new services and for codes for which definitions have changed.

(2) HCFA 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, HCFA 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) HCFA 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, HCFA 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 HCFA 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.

HCFA establishes a GAF for each service in each fee schedule area.

(a) *Geographic indices.* HCFA 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.

HCFA establishes CFs in accordance with section 1848(d) of the Act.

(a) *Base-year CFs.* HCFA 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 physician 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.

(b) *General rule.* If physician services of the type routinely furnished in physician offices are furnished in facility settings, the fee schedule amount for those services is determined by reducing the practice expense RVUs for the service by 50 percent.

(c) *Services covered by the reduction.* HCFA 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]

§ 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.

(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) HCFA 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.

§ 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.

§ 414.38 Special rules for payment of low osmolar contrast media.

(a) *General.* Payment for low osmolar contrast media is included in the technical component payment for diagnostic procedures except as specified in paragraph (b) of this section.

(b) *Conditions for separate payment.* For diagnostic procedures furnished to beneficiaries who are neither inpatients nor outpatients of any hospital,

separate payment is made for low osmolar contrast media used in all intrathecal injections and in intravenous, and intra-arterial injections, if it is used for patients with one or more of the following characteristics:

(1) A history of a previous adverse reaction to contrast material, with the exception of a sensation of heat, flushing, or a single episode of nausea or vomiting.

(2) A history of asthma or allergy.

(3) Significant cardiac dysfunction including recent or imminent cardiac decompensation, severe arrhythmias, unstable angina pectoris, recent myocardial infarction, and pulmonary hypertension.

(4) Generalized severe debilitation.

(5) Sickle cell disease.

(c) *Method of payment.* If one of the conditions of paragraph (b) of this section is met, payment is made for low osmolar contrast media as set forth in § 414.36 as a drug furnished incident to a physician's service, subject to paragraph (d) of this section.

(d) *Drug payment reduction.* If separate payment is made for low osmolar contrast media, the payment amount calculated in accordance with § 414.36 is reduced by 8 percent to account for the allowance for contrast media already included in the technical component of the diagnostic procedure code.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42492, 42493, Sept. 15, 1992]

§ 414.39 Special rules for payment of care plan oversight.

(a) *General.* Except as specified in paragraph (b) of this section, payment for care plan oversight is included in the payment for visits and other services under the physician fee schedule.

(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.

[59 FR 63463, Dec. 8, 1994; 60 FR 49, Jan. 3, 1995; 60 FR 36733, July 18, 1995]

§ 414.40 Coding and ancillary policies.

(a) *General rule.* HCFA establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes.

(b) *Specific types of policies.* HCFA 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 HCFA 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.* HCFA 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 pre-operative and post-operative visits, the administration of fluids and/or blood incident to anesthesia care, and monitoring services.

(2) *Time units* involve the continuous actual presence of the physician (or of the medically directed qualified anesthetist or resident) and start when he or she begins to prepare the patient for anesthesia care and ends when the anesthesiologist (or medically directed CRNA) is no longer in personal attendance, that is, when the patient may be safely placed under post-operative care.

(b) *Determination of payment amount—Basic rule.* For anesthesia services performed, medically directed, or medically supervised by a physician, HCFA pays the lesser of the actual charge or the anesthesia fee schedule amount.

(1) The physician fee schedule amount for an anesthesia service is based on the product of the allowable base and time units and an anesthesia-specific CF.

(2) The allowable base units are determined by the uniform relative value guide based on 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. The uniform base units are identified in program operating instructions.

(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) HCFA 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) HCFA 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) HCFA 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) *Physician medically supervises anesthesia services.* If the physician medically supervises more than four concurrent anesthesia services, HCFA 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.

(f) *Payment for medical or surgical services furnished by a physician while furnishing anesthesia services.* (1) HCFA 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. HCFA 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) HCFA 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.

(g) *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.

[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]

§ 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 HCFA 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.

[58 FR 63687, Dec. 2, 1993]

§ 414.50 Physician billing for purchased diagnostic tests.

(a) *General rule.* 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, HCFA 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.

§ 414.52 Payment for physician assistants' services.

Allowed amounts for the services of a physician assistant furnished beginning January 1, 1992, may not exceed the following limits:

(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.

§ 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, allowed amounts for the services of a nurse practitioner or a clinical nurse specialist in 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, 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.

[56 FR 59624, Nov. 25, 1991, as amended at 57 FR 42493, Sept. 15, 1992]

§ 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, HCFA 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.* 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, rural primary care 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]

Subparts B–C—[Reserved]

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 HCFA 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) HCFA 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 HCFA 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 HCFA 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) HCFA 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) HCFA 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, HCFA 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) HCFA 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 § 413.170 of this chapter.

(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 HCFA, 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.

§ 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 (§ 413.170) 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]

§ 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) HCFA 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 HCFA 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 HCFA that he or she has only one supplier for all home dialysis equipment and supplies. This certification is made on HCFA 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 HCFA 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 HCFA 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 HCFA, plus the median cost per treatment for all dialysis facilities for laboratory tests included under the composite rate, as determined by HCFA, 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 HCFA 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–H—[Reserved]

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

Subpart A—General Provisions

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415.1 Basis and scope.

Subpart B—Fiscal Intermediary Payments to Providers for Physician Services

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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 §413.86 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.

§ 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), HCFA 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, HCFA 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 §413.86 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.* HCFA 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, HCFA publishes a notice in the FEDERAL REGISTER that sets forth the amount of the limits and explains how it calculated the limits.

(2) If HCFA proposes to revise the methodology for establishing payment limits under this section, HCFA 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 HCFA updates limits by applying the most recent economic index data without revising the limit methodology, HCFA publishes the revised limits in a notice in the FEDERAL REGISTER without prior publication of a proposal or public comment period.

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 § 413.86 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), HCFA 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).

§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: Anesthesiology services.

(a) *Services furnished directly or concurrently.* The carrier pays a physician for anesthesia services furnished to patients in a provider on a fee schedule basis only if the services meet the conditions 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 procedures in the anesthesia plan, including 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 program 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 performs the procedure personally or directs no more than four anesthesia procedures concurrently and does not perform any other services while he or she is directing the concurrent procedures.

(b) *Supervision of more than four procedures concurrently.* If a physician is involved in furnishing more than four procedures concurrently, or is performing other services while directing the concurrent procedures, the concurrent anesthesia services are physician services to the provider in which the procedures are performed. In these cases, the physician is not required to meet the criteria of paragraphs (a)(1) (iii) and (vii) of this section personally, but must ensure that a qualified individual performs any procedure in which the physician does not personally participate. In these cases, the intermediary pays for the services under the rules in §§ 415.55 and 415.60 on reasonable cost payment for physician services to providers or under the rules in part 412 of this chapter for payment under the prospective payment system.

§ 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) *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 (b) of this section.

(4) Clinical laboratory interpretative services that meet the requirements of paragraphs (b)(1), (b)(3), and (b)(4) of this section and that are specifically listed in program operating instructions.

(b) *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.

(c) *Physician pathology services furnished by an independent laboratory.* Laboratory services, including the technical component of a service, furnished to a hospital inpatient or outpatient by an independent laboratory are paid on a fee schedule basis under this subpart only if they are physician pathology services as described in paragraph (a) of this section.

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 § 413.86 of this chapter.

(c) Physician services to beneficiaries under the physician fee schedule as set forth in part 414 of this chapter.

§ 415.152 Definitions.

As used in this subpart—

Approved graduate medical education (GME) program means 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 Council on Dental Education of the American Dental Association, or by the Council on Podiatric Medicine Education of the American Podiatric Medical Association.

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 § 413.86, 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.

§ 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 § 413.86 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 § 413.86.

§ 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 HCFA 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) HCFA 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 x 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 HCFA.

(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 x 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 HCFA under part 489 of this chapter.

(3) The intermediary, or HCFA 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 HCFA 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

HCFA 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 § 413.86.

(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, diagnosis, or gender.

(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.

§ 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 HCFA 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 § 413.86 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.

§ 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 § 413.86 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.

§ 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 § 413.86(f)(1)(iii) 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.

§ 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 § 413.86 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 (§ 413.86 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).

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 HCFA 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 HCFA 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.* HCFA 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 HCFA 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 HCFA, of the findings of the accreditation survey.

(b) *Survey of ASCs.* (1) Unless HCFA 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 HCFA.

(2) HCFA surveys deemed ASCs on a sample basis as part of HCFA's validation process.

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services.* If HCFA 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 HCFA.

(e) *Acceptance by HCFA.* If HCFA 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 HCFA refuses to enter into an agreement or if HCFA 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 HCFA.

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 HCFA 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 HCFA is in effect.

(d) *Furnishing information.* The ASC agrees to furnish to HCFA, if requested, information necessary to establish payment rates specified in §§ 416.120–416.130 in the form and manner that HCFA 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 HCFA 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 HCFA 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 HCFA.* An ASC that wishes to terminate its agreement must send HCFA 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 HCFA, HCFA may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) HCFA 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

[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.

voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) *Termination by HCFA*—(1) *Cause for termination.* HCFA 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.* HCFA 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 HCFA has approved or set a termination date; or

(2) HCFA, when it has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by HCFA.* When an agreement with an ASC is terminated by HCFA, the ASC may not file another agreement to participate in the Medicare program unless HCFA—

(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 or an anesthesiologist's assistant as defined in §410.68(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician

administers the anesthesia, 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.

[57 FR 33899, July 31, 1992]

§ 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 provided in paragraphs (b) (2) and (3) of this section, the ASC must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference)[1] that are applicable to ambulatory surgical centers.

(2) In consideration of a recommendation by the State survey agency, HCFA 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) Any ASC that, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard, so long as the ASC continues to remain in compliance with that edition of the Life Safety Code.

(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]

§ 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.

[1] See footnote to § 405.1134(a) of this chapter.

(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.* HCFA 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 HCFA proposes to revise the payment rate for ASCs, HCFA 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, HCFA publishes a notice establishing the rates authorized by this section. In setting these rates, HCFA 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, HCFA conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) HCFA 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 HCFA's survey request, HCFA may terminate the agreement to participate in the Medicare program as an ASC.

(4) HCFA 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 HCFA, 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 HCFA submit, in the form and detail as may be required by HCFA, 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.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

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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 HCFA 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 HCFA, 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 HCFA 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, and 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, HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA,

(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. HCFA will review the factors used by each HMO to establish classes under paragraph (b)(2)(i) of this section. If HCFA determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, HCFA 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 HCFA 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 HCFA. HCFA 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 HCFA, listing the factors to be used in the community rating by class system under paragraph (b)(2) of this section.

(2) HCFA 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 HCFA will notify the HMO of its decision within 30 days from the date of receipt of this information or data; or

(iii) HCFA needs additional time to review the written request and the HMO will be notified of HCFA'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 HCFA 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 HCFA 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 HCFA 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 HCFA.

(iii) Financial reserves, acceptable to HCFA, that are held for the HMO and restricted for use only in the event of insolvency.

(iv) Any other arrangements acceptable to HCFA.

(2) The requirements of this paragraph do not apply to an HMO if HCFA 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 HCFA, 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 HCFA 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 HCFA, to its enrollees, and to the general public, at the times and in the manner that HCFA 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 HCFA may require.

(b) *Significant business transactions.* Each HMO must report to HCFA annually, within 120 days of the end of its fiscal year (unless for good cause shown, HCFA 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, HCFA 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, HCFA 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 HCFA follows to make determinations; and

(c) Other related provisions, including application fees.

[59 FR 49836, Sept. 30, 1994]

§ 417.141 Definitions.

As used in this subpart—

Operational qualified HMO means an HMO that HCFA has determined provides basic and supplemental health services to all of its enrollees in accordance with subpart B of this part and §§ 417.168 and 417.169, and is organized and operated in accordance with subpart C of this part and §§ 417.168 and 417.169.

Preoperational qualified HMO means an entity that HCFA has determined will, when it becomes operational, be a qualified HMO.

Transitionally qualified HMO means an entity that operates a prepaid health care delivery system and that HCFA has determined meets the requirements of § 417.142(b). A transitionally qualified HMO is considered a ''qualified HMO'' for the purpose of compliance by an employer with the requirements of section 1310 of the PHS Act and subpart E of this part. Under these requirements, the employer must include the HMO in its health benefits plan so long as the HMO's qualification has not been revoked under section 1312(b) of the PHS Act and § 417.163(d).

[58 FR 38070, July 15, 1993]

§ 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) HCFA 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 HCFA may require.

(3) HCFA 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.* HCFA determines that an entity is an operational qualified HMO if—

(1) HCFA finds that the entity meets the requirements of subparts B and C of this part.

(2) The entity, within 30 days of HCFA's determination, provides written assurances, satisfactory to HCFA, 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 HCFA 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 HCFA.

(c) *Preoperational qualified HMO.* (1) HCFA may determine that an entity is a preoperational qualified HMO if it provides, within 30 days of HCFA'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, HCFA 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.* HCFA 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 HCFA'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 HCFA'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 HCFA's determination, and which are renewed or renegotiated during the period approved by HCFA 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 HCFA that—

(A) May not extend for more than 3 years from the date of HCFA'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 HCFA's determination.* The entity gives assurances that, with respect to any group or individual contract entered into after the date of HCFA'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 HCFA 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, HCFA 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 HCFA.

(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, HCFA 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, HCFA 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.* HCFA refunds an application fee only if the entity withdraws its application within 10 working days after receipt by HCFA. 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 HCFA determines that a change in the amount of a fee is appropriate, HCFA 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 HCFA 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, and amended at 58 FR 38077, July 15, 1993]

§ 417.144 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) HCFA evaluates an application for Federal qualification on the basis of information contained in the application itself and any additional information that HCFA obtains through onsite visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, HCFA 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, HCFA determines whether the entity meets the applicable requirements of §§ 417.142 and 417.143.

(b) *Notice of determination.* HCFA 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 HCFA 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, HCFA 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 HCFA's preliminary finding, and may revise its application to remedy any defects identified by HCFA.

(d) *Denial and reconsideration of denial.* (1) If HCFA denies an application for qualification under this subpart, HCFA 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 HCFA 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) HCFA 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 HCFA.

(4) HCFA 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, HCFA 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

[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.

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]

§ 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 HCFA 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) *HCFA review of data.* (1) HCFA 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 HCFA'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 HCFA 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 HCFA, 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 HCFA under § 417.126, and

(b) Any additional reports HCFA 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 HCFA 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) HCFA may initiate investigations when, based on a report, a complaint, or any other information, HCFA 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 HCFA 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) HCFA 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 HCFA considers appropriate in seeking this information.

(c) *Determination and notice by HCFA*—(1) *Determination.* (i) On the basis of the investigation, HCFA determines whether the HMO has failed to comply with any of the assurances it gave under subpart D of this part.

(ii) HCFA publishes in the FEDERAL REGISTER a notice of each determination of non-compliance.

(2) *Notice of determination: Corrective action.* (i) HCFA 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 HCFA 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 HCFA, or within any longer period that HCFA determines to be reasonable and specifies in the notice. The HMO must carry out the corrective action within the time period specified by HCFA in the notice.

(iv) The notice may provide the HMO an opportunity to submit, for HCFA's approval, proposed methods for achieving compliance.

(d) *Remedy: Revocation of qualification.* If HCFA 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) HCFA revokes the HMO's qualification and notifies the HMO of this action.

(2) In the notice, HCFA 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 HCFA receives a request for reconsideration by that date.

(4) If after reconsideration HCFA 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) HCFA 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 HCFA 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 HCFA determines, under paragraph (c)(1) of this section, that an HMO is out of compliance, HCFA 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 HCFA 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, HCFA 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 HCFA 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.* HCFA 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 HCFA 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 HCFA waives any assurances regarding compliance with section 1301 of the PHS Act, HCFA 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]

§ 417.168 Special requirements: titles XVIII and XIX of the Social Security Act.

(a) As provided in section 1307(d) of the PHS Act, an HMO that otherwise complies with section 1301(b) and section 1301(c) of the PHS Act, and with the applicable regulations of subparts B and C of this part and § 417.169, and that has enrollees who are entitled to insurance benefits under title XVIII of the Act or to medical assistance under a State plan approved under title XIX of the Act, may still be considered to be an HMO if, with respect to its title XVIII and title XIX enrollees, it provides services and is operated as required by title XVIII or title XIX, as appropriate, and by implementing regulations.

(b) Notwithstanding any inconsistent requirements of subparts B and C of this part and § 417.169, an HMO that enters into a contract with HCFA under title XVIII of the Act or with a State under title XIX of the Act must, with respect to its enrollees entitled to insurance benefits or medical assistance under those titles, comply with the applicable title XVIII or title XIX requirements, including deductible and coinsurance requirements, enrollment mix and enrollment practice requirements, in accordance with the provisions of title XVIII or the title XIX State plan of the State with which it is contracting. Copayment options that are not in accordance with a title XIX State plan may not be imposed on title XIX enrollees.

(c) Any grievance procedures authorized under title XVIII or title XIX of

the Act are not superseded by the provisions of § 417.124(g).

[58 FR 38071, July 15, 1993]

§ 417.169 Special requirements: Federal employee health benefits program.

An entity that provides health services to a defined population on a prepaid basis and that has enrollees who are enrolled under the health benefits program authorized by Chapter 89 of Title 5, United States Code, may be considered to be an HMO for purposes of receiving assistance under this part if, with respect to its other enrollees, it—

(a) Provides health services in accordance with section 1301(b) of the Act, subpart B of this part, and § 417.168; and

(b) Is organized and operated in the manner prescribed by section 1301(c) of the PHS Act, subpart C of this part, and § 417.168.

[58 FR 38072, July 15, 1993]

Subpart 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 HCFA 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 HCFA under section 1876 of the Act. It also specifies the procedures that HCFA 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 HCFA 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 HCFA, 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 HCFA 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 HCFA 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 HCFA 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 HCFA records as an enrollee of an HMO or CMP that has a contract with HCFA 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 HCFA 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 HCFA 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.

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.

[58 FR 38072, July 15, 1993]

§ 417.404 General requirements.

(a) In order to contract with HCFA under the Medicare program, an entity must—

(1) Be determined by HCFA 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) HCFA 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.* HCFA 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.* HCFA 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) HCFA 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, HCFA 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 HCFA. (2) Whenever feasible, HCFA exempts the HMO or CMP from resubmittal of information it has already submitted to HCFA in connection with a determination made under the provisions of § 417.406.

(b) *Approval of application.* (1) If HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 and Medicaid recipients.

(2) *Waiver of composition of enrollment standard.* HCFA 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 or Medicaid recipients, and it meets either 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. (HCFA 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.

(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 HCFA.

(i) If HCFA 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, HCFA may extend the waiver of modification.

(ii) If HCFA determines that the HMO or CMP has not complied with the approved schedule, HCFA may apply the sanctions described in paragraphs (d)(6) and (d)(7) of this section.

(4) *Basis for application of sanctions.* HCFA may, as an alternative to contract termination, apply the sanctions specified in paragraph (d)(6) of this section if HCFA 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, HCFA sends a written notice to the HMO or CMP stating the proposed action and its basis. HCFA 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

HCFA's notice, HCFA determines that an HMO or CMP does not comply with the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section, HCFA may apply either of the following sanctions:

(i) Require the HMO or CMP to stop accepting new enrollment applications after a date specified by HCFA.

(ii) Deny payment for individuals who are formally added or ''accreted'' to HCFA's records as Medicare enrollees after a date specified by HCFA.

(7) *Termination by HCFA.* In addition to the sanctions described in paragraph (d)(6) of this section. HCFA 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 HCFA determines that the HMO or CMP no longer substantially meets the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section.

(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) HCFA 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 HCFA. 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]

§ 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 a risk HMO or CMP, services of clinical psychologists, and services and supplies incident to their professional services. For purposes of this section, a clinical psychologist is an individual who—

(i) Holds a doctoral degree in psychology from an educational institution that is accredited by an organization recognized by the Council on Post-Secondary Accreditation;

(ii) Is licensed or certified at the independent practice level of psychology in the State in which he or she practices; and

(iii) Has 2 years of supervised clinical experience at least l of which is postgraduate.

(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]

§ 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 other wise 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 HCFA under subpart L of this part.

(b) *Entitlement.* If a Medicare beneficiary enrolls with an HMO or CMP, HCFA 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 HCFA 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 HCFA. (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 HCFA 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.

(b) *Capacity to accept new enrollees.* (1) If an HMO or CMP chooses to limit enrollments because of its capacity, it must notify HCFA at least 90 days before the beginning of its open enrollment period and, at that time, provide HCFA with its reasons for limiting enrollment.

(2) HCFA evaluates the HMO's or CMP's submittal under paragraph (b)(1) of this section.

(3) The HMO or CMP must promptly notify HCFA if there is any change in its enrollment capacity.

(c) *Reserved vacancies.* (1) Subject to HCFA'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]

§ 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 HCFA 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 HCFA, that

HCFA 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 HCFA. For example, the HMO or CMP may not claim that it is recommended or endorsed by HCFA or that HCFA 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 HCFA that HCFA has disapproved the material because it is inaccurate or misleading or it misrepresents the HMO or CMP, its marketing representatives or HCFA.

(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 HCFA instructions regarding format and content and must include the beneficiary's signature and authorization for disclosure and exchange of necessary information between HCFA and the HMO or CMP.

(2) The HMO or CMP must file and retain application forms for the period specified in HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA.

(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 HCFA.* The HMO or CMP must notify HCFA, within the following time frames, of the enrollee's authorization for disclosure and exchange of information and the information necessary for HCFA 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 HCFA and notice that both HCFA 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 HCFA 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 HCFA 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 enrollee.* 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, and, for risk HMOs or CMPs, in addition to the additional benefits required under § 417.442. The HMO or CMP may not set health status standards for those enrollees whom it will accept for these optional supplemental services.

(3) *Supplemental services imposed by a risk HMO or CMP.* (i) Subject to HCFA'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) HCFA approves supplemental benefits of this type if HCFA 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, HCFA 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]

§ 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 HCFA 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 HCFA 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 HCFA 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 HCFA determination.* If HCFA 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) HCFA 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) HCFA'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 HCFA receives the information necessary to include the beneficiary as a Medicare enrollee of the HMO or CMP in HCFA records.

(b) *Exceptions.* (1) HCFA 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 HCFA's records as an enrollee of an HMO or CMP, HCFA gives the HMO or CMP prompt written notice of the month with which HCFA'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 PRO 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 PRO 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 HCFA 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 HCFA.* 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, HCFA 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 HCFA 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 HCFA 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 HCFA.

(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 HCFA.

(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) *HCFA review of an HMO's or CMP's proposed disenrollment for cause.* (i) HCFA decides on the basis of review of the documentation submitted by the HMO or CMP, whether disenrollment requirements have been met.

(ii) HCFA 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 HCFA 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 HCFA, 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 HCFA 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 HCFA 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 HCFA.

(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 HCFA 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 HCFA pays for services not provided or arranged for by the HMO or CMP.

(c) *Effect of failure to submit disenrollment notice to HCFA 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 HCFA 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 HCFA's liability for payment: Disenrollment of beneficiaries and termination or default of contract.

(a) *Effect of disenrollment: General rule.* (1) HCFA'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 HCFA'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 HCFA 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, HCFA'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, HCFA'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, HCFA'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, HCFA'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 HCFA and the HMO or CMP is terminated by mutual consent or by unilateral action of either party, HCFA'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, HCFA—

(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 1876(c), (g), (h), and (i) of the Act that pertain to the contract between HCFA 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]

§ 417.472 Basic contract requirements.

(a) *Submittal of contract.* An HMO or CMP that wishes to contract with HCFA to furnish services to Medicare beneficiaries must submit a signed contract that meets the requirements of this subpart and any other requirements established by HCFA.

(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 HCFA.

(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 HCFA 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, HCFA 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.

[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]

§ 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 HCFA 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 HCFA 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 HCFA.

[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 PRO 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 CMPs and individual physicians or physician groups with whom they contract to provide medical services to enrollees. 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 or is greater than 25,000 patients only as a result of pooling patients using a method set forth in paragraph (h)(1)(v) of this section:

(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 possible payments and minimum possible payments is more than 25 percent of the maximum possible payments; or

(ii) The maximum and minimum possible 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 incentive plan, and at least every 2 years 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. In determining patient panel size, the patients may be pooled using one of the methods set forth in paragraph (h)(1)(v) of this section if pooling is consistent with the relevant contract between the physician or physician group and the HMO or CMP. 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:

(A) Less than 1,000 patients—$10,000.

(B) 1,000 to 10,000 patients—$30,000.

(C) 10,000 to 25,001 patients—$200,000.

(D) Greater than 25,000 patients—

(*1*) Without pooling patients—none; and

(*2*) As a result of pooling patients—$200,000.

(iii) The HMO or CMP may provide the stop-loss protection directly or purchase the stop-loss protection, or the physician or physician group may purchase the stop-loss protection. If the physician or physician group purchases the stop-loss protection, the HMO or CMP must pay the portion of the premium that covers its enrollees or reduce the level at which the stop-loss protection applies by the cost of the stop-loss.

(h) *Disclosure requirements for organizations with physician incentive plans*—(1) *Disclosure to HCFA.* Each HMO or CMP must provide to HCFA information concerning its physician incentive plans as required or requested. The disclosure must contain the following information in detail sufficient to enable HCFA to determine whether the incentive plan complies with the requirements specified in this section:

(i) Whether services not furnished by the physician or physician group are covered by the incentive plan. If only the services furnished by the physician or physician group are covered by the incentive plan, disclosure of other aspects of the plan need not be made.

(ii) The type of incentive arrangement; for example, withhold, bonus, capitation.

(iii) If the incentive plan involves a withhold or bonus, the percent of the withhold or bonus.

(iv) The amount and type of stop-loss protection.

(v) The panel size and, if patients are pooled according to one of the following permitted methods, the method used:

(A) Including commercial, Medicare, and/or Medicaid patients in the calculation of the panel size.

(B) Pooling together, by the HMO or CMP, of several physician groups into a single panel.

(vi) In the case of capitated physicians or physician groups, capitation payments paid to primary care physicians for the most recent year broken down by percent for primary care services, referral services to specialists, and hospital and other types of provider (for example, nursing home and home health agency) services.

(vii) In the case of those prepaid plans that are required to conduct beneficiary surveys, the survey results.

(2) *When disclosure must be made to HCFA.* (i) An HMO or CMP must provide the information required by paragraph (h)(1) of this section to HCFA—

(A) Upon application for a contract;

(B) Upon application for a service area expansion; and

(C) Within 30 days of a request by HCFA.

(ii) An HMO or CMP must notify HCFA at least 45 days before implementing any of the following changes in its incentive plan:

(A) A change as to the type of incentive plan.

(B) A change in the amounts of risk or stop-loss protection.

(C) Expansion of the risk formula to cover services not furnished by the physician group that the formula had not included previously.

(3) *Disclosure to Medicare beneficiaries.* An HMO or CMP 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 HCFA 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 HCFA 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.* HCFA may apply intermediate sanctions, or the Office of Inspector General may apply civil money penalties described at § 417.500, if HCFA 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]

§ 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 HCFA 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 HCFA 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) HCFA 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) HCFA 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 HCFA—

(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 HCFA 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 HCFA 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 HCFA 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) HCFA 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 HCFA.* (1) *Notice of nonrenewal.* If HCFA 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.* HCFA gives the HMO or CMP written notice of its right to appeal the nonrenewal decision, in accordance with subpart R of this part, if HCFA'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) HCFA 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 HCFA determines are appropriate for notification.

(3) If the contract is terminated, the HMO or CMP must notify its Medicare enrollees, and HCFA notifies the general public, at least 30 days before the termination date.

(b) *Termination by HCFA.* (1) HCFA 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) HCFA 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 HCFA 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) HCFA 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 HCFA has failed substantially to carry out the terms of the contract.

(1) The HMO or CMP must notify HCFA 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) HCFA'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.* HCFA may impose the intermediate sanctions specified in paragraph (d) of this section, as an alternative to termination of contract, if HCFA 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 HCFA, 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, HCFA—

(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.* HCFA 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. HCFA 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 HCFA before the end of the 15-day period following the date of receipt of the sanction notice. HCFA 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 HCFA's notice of sanction, HCFA conducts an informal reconsideration that:

(1) Consists of a review of the evidence by a HCFA 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 HCFA 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, HCFA 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 HCFA's reconsidered determination.

(2) *Exception.* If HCFA determines that the HMO's or CMP's conduct poses a serious threat to an enrollee's health and safety, HCFA may make the sanction effective on a date before issuance of HCFA's reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until HCFA notifies the HMO or CMP that HCFA is satisfied that the basis for imposing the sanction has been corrected and is not likely to recur.

(f) *Termination by HCFA.* In addition to or as an alternative to the sanctions described in paragraph (d) of this section, HCFA 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 HCFA 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), HCFA notifies the OIG of that determination. HCFA 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 HCFA 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 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) *Unincorporated sole proprietor.* Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation.* (i) The merger of the HMO's or CMP's corporation into another corporation or the consolidation of the HMO or CMP 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 HMO's or CMP's corporation, with the HMO or CMP surviving, does not ordinarily constitute change of ownership.

(b) *Advance notice requirement.* (1) An HMO or CMP that has a Medicare contract in effect and is considering or negotiating a change in ownership must notify HCFA at least 60 days before the anticipated effective date of the change.

(2) If the HMO or CMP fails to give HCFA the required notice timely, it continues to be liable for capitation payments that HCFA 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 HMO or CMP, the prospective new owner, and HCFA—

(1) That is embodied in a document executed and signed by all three parties;

(2) That meets the requirements of § 417.522; and

(3) Under which HCFA 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 L of this part.

(e) *Effect of change of ownership with novation agreement.* If the HMO or CMP submits a novation agreement that meets the requirements of § 417.522, and HCFA signs it, the new owner becomes the successor in interest to the current owner's Medicare contract.

[60 FR 45681, Sept. 1, 1995]

§ 417.522 Novation agreement requirements.

(a) *Conditions for HCFA approval of a novation agreement.* HFCA approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The HMO or CMP notifies HCFA at least 60 days before the date of the proposed change of ownership.

(2) *Advance submittal of agreement.* The HMO or CMP submits to HCFA, 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 HCFA.

(3) *HCFA's determination.* HCFA 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 HMO or CMP under subpart J 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 HCFA.

(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 HCFA 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]

§ 417.523 Effect of leasing of an HMO's or CMP's facilities.

(a) *General effect of leasing.* If an HMO or CMP leases all or part of its facilities to another entity, the other entity does not acquire HMO or CMP status under section 1876 of the Act.

(b) *Effect of lease of all facilities.* (1) If an HMO or CMP leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as an HMO or CMP, it must apply for and enter into a contract in accordance with subpart L of this part.

(c) *Effect of partial lease of facilities.* If the HMO or CMP leases part of its facilities to another entity, its contract with HCFA remains in effect while HCFA surveys the HMO or CMP to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart J of this part.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985; 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995]

Subpart N—Medicare Payment to HMOs and CMPs: General Rules

§ 417.524 Payment to HMOs or CMPs: General.

(a) *Basic rule.* The payments that HCFA 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 HCFA 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) HCFA 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 HCFA.

(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 HCFA 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; 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) HCFA 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, HCFA 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 HCFA 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, HCFA 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, HCFA generally applies the cost payment principles set forth in § 413.5 of this chapter.

(3) In judging whether costs are reasonable, HCFA 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) HCFA 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) HCFA 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, HCFA 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 HCFA.

(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 HCFA.

(f) *Review of HMO's or CMP's bill processing capabilities.* If the HMO or CMP elects to pay providers directly, HCFA 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 HCFA.* (1) If the HMO or CMP elects to have HCFA pay for provider services, HCFA 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, HCFA 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.* HCFA 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 HCFA 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.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993]

§ 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 HCFA 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.* HCFA 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.* HCFA 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 HCFA 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 HCFA 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 HCFA.

(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 HCFA 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 HCFA 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 HCFA'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 HCFA. HCFA 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 HCFA) 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 HCFA approval at least 90 days before the beginning of the period for which the different method is to be used.

(2) If HCFA approves use of a different method, the HMO or CMP may not revert to another method without first obtaining HCFA'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 HCFA 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 HCFA.

(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 HCFA statistical, financial, and other information with respect to those services in the form and detail prescribed by HCFA.

[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) HCFA makes monthly advance payments equivalent to the HMO's or CMP's interim per capita rate for each beneficiary who is registered in HCFA 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 HCFA'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 HCFA 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, HCFA 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, HCFA 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 HCFA 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 HCFA, 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 HCFA 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, HCFA 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 HCFA. These interim cost reports must be submitted no later than 60 days after the close of each quarter of the contract period.

(2) HCFA may reduce the frequency of the reports required under paragraph

(c)(1) of this section if HCFA 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, HCFA 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. HCFA will base the determination on the interim cost report and enrollment data submitted by the HMO or CMP, and any other relevant data HCFA finds appropriate. For this purpose, HCFA 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 HCFA, whichever is appropriate, no later than 30 days after HCFA'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 HCFA'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 HCFA an independently certified cost report and supporting documents, in the form and detail required by HCFA, no later than 180 days after the end of each contract period, unless HCFA 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 HCFA.

(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 HCFA under paragraph (b)(1) of this section), HCFA 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, HCFA 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 HCFA 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) HCFA 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 HCFA 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 HCFA'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) HCFA'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 HCFA to refund the overpaid amount.

(iii) HCFA, 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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, HCFA makes payment for covered services only to the HMO or CMP.

(a) *Principle of payment.* HCFA makes monthly advance payments equivalent to the HMO's or CMP's per capita rate of payment for each beneficiary who is registered in HCFA 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) HCFA 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, HCFA 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), HCFA reduces the amount of payment by the appropriate amount.

[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]

§ 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 HCFA 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, HCFA 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, HCFA informs the HMO or CMP of the specific adjustment factors it will use in computing the AAPCC.

(c) *Adjustment factors.* (1) *Geographic.* HCFA 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 HCFA when it makes the determination.

(2) *Enrollment.* HCFA 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.* HCFA 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, HCFA 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, HCFA 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 HCFA.* If the HMO or CMP claims to have insufficient enrollment experience to make the computations required by paragraph (a) of this section, and HCFA agrees with the claim, HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA.* (1) The HMO or CMP must give HCFA 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 HCFA, 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 HCFA 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 HCFA 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 HCFA.* 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, HCFA will, at the HMO's or CMP's request, adjust the initial rate. HCFA 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 HCFA further reduces the adjusted rates by the actuarial value of applicable Medicare deductibles and coinsurance.

(e) *HCFA review.* (1) *Submission of data.* The HMO or CMP must submit its ACR and the methodology used to compute it for HCFA review and approval, and must include adequate supporting data.

(2) *Appeals procedures.* (i) If HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA.* 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 HCFA 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, HCFA 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 HCFA 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.* HCFA may grant an exception to the limit described in paragraph (c)(1) of this section if an HMO or CMP can demonstrate to HCFA'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 HCFA 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 HCFA 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 HCFA.* 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 HCFA 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 HCFA approval.* HCFA 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.* HCFA 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.

HCFA's payment to an HMO or CMP may be subject to an enrollment reconciliation at least annually. HCFA 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 HCFA 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 hearing and to judicial review for any individual dissatisfied with a determination regarding his or her Medicare benefits.

(2) Section 1876 of the Act provides for Medicare payments to HMOs and CMPs that contract with HCFA to enroll Medicare beneficiaries and furnish Medicare-covered health care services to them. Section 1876(c)(5) provides that—

(i) An HMO or CMP must establish grievance and appeals procedures; and

(ii) Medicare enrollees dissatisfied because they do not receive health care services to which they believe they are entitled, at no greater cost than they believe they are required to pay, have the following appeal rights:

(A) The right to an ALJ hearing if the amount in controversy is $100 or more.

(B) The right to judicial review of the hearing decision if the amount in controversy is $1000 or more.

(iii) The Medicare enrollee and the HMO or CMP are parties to the hearing and to the judicial review.

(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 that all Medicare enrollees have a complete written explanation of their grievance and appeal rights, of the steps to follow, and of the time limits for each step of the procedures; and

(4) The special rules that apply when a beneficiary requests immediate PRO review of a determination that he or she no longer needs inpatient hospital care.

[60 FR 46233, Sept. 6, 1995]

§ 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]

§ 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 PRO 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 PRO 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.

(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]

§ 417.605 Immediate PRO 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 PRO review of the determination.

(b) *Procedures.* For the immediate PRO review process, the following rules apply:

(1) The enrollee or authorized representative must submit the request for immediate review—

(i) To the PRO 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 PRO 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 PRO 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 PRO by close of business of the first full working day immediately following the day the HMO or CMP makes its request.

(5) The PRO must solicit the views of the enrollee who requested the immediate PRO review (or the enrollee's representative).

(6) The PRO 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 PRO 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 PRO review; and

(ii) The PRO upholds the noncoverage determination made by the HMO or CMP.

[59 FR 59941, Nov. 21, 1994]

§ 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.

(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]

§ 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 within 60 days of receiving the enrollee's request for payment for services.

(b) The notice must—

(1) State the specific reasons for the determination; and

(2) Inform the enrollee of his or her right to reconsideration.

(c) The failure to provide the enrollee with timely notification of an adverse organization determination constitutes an adverse organization determination and may be appealed.

[50 FR 1346, Jan. 10, 1985, as amended at 59 FR 59942, Nov. 21, 1994]

§ 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]

§ 417.612 Effect of organization determination.

The organization determination is final and 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]

§ 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.

[59 FR 59942, Nov. 21, 1994]

§ 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.

(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, HCFA, 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]

§ 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.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38083, July 15, 1993; 59 FR 59942, Nov. 21, 1994]

§ 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. HCFA makes the reconsidered datermination.

(c) The HMO or CMP must issue the reconsidered determination to the enrollee, or submit the explanation and file to HCFA, within 60 calendar days from the date of receipt of the request for reconsideration.

(d) For good case shown, HCFA may allow expeditions 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 60-day limit 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 HCFA.

(f) If the HMO or CMP refers the matter to HCFA, it must concurrently notify the beneficiary of that action.

[59 FR 59942, Nov. 21, 1994]

§ 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 HCFA 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]

§ 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 HCFA, for sending a copy to HCFA.

(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]

§ 417.626 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 the provisions of § 417.632, or unless it is revised in accordance with § 417.638.

[50 FR 1346, Jan. 10, 1985]

§ 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]

§ 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 a presiding officer 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]

§ 417.634 Departmental Appeals Board review.

Any party to the hearing, including the HMO or CMP, who is dissatisfied with the hearing decision, may request the Departmental Appeals Board to review the ALJ's decision or dismissal. Provisions regarding Departmental Appeals Board review are contained in 20 CFR 404.967 through 404.983.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985; 58 FR 38083, July 15, 1993, as amended at 61 FR 32348, June 24, 1996]

§ 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 HCFA; 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]

§ 417.638 Reopening determinations and decisions.

An organization, reconsidered, or revised determination made by an HMO, CMP, or HCFA, 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]

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 HCFA 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, HCFA'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 HCFA 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) HCFA 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) HCFA 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 HCFA 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.* HCFA 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 HCFA. If HCFA approves, the request for reconsideration is withdrawn.

§ 417.652 Opportunity to submit evidence.

HCFA 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) HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA.

(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) HCFA.

[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 HCFA 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 HCFA 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.

HCFA 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, HCFA 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 HCFA.

[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 HCFA 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 HCFA, and general instructions issued by HCFA 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 HCFA 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 HCFA 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—

(1) Is responsible for the organization, financing and delivery of covered Part B services to a defined population on a prepayment basis;

(2) Meets the conditions specified in paragraph (b) of this section; and

(3) Elects to be reimbursed on a reasonable cost basis.

Medicare enrollee means a beneficiary under Part B of Medicare who has been identified on HCFA records as an enrollee of the HCPP. *Reporting period* means the period specified by HCFA 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 HCFA 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 HCFA as required by § 417.801.

(c) *Payment of reasonable cost.* (1) Except as otherwise provided in this subpart, HCFA 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, HCFA 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, HCFA 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. HCFA 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. HCFA 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.* HCFA 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]

§ 417.801 Agreements between HCFA 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 HCFA.

(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 HCFA 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 HCFA 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 HCFA.

(d) *Termination or nonrenewal of agreement by HCFA.* (1) HCFA 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 HCFA 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) HCFA 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 HCFA 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 HCFA stating the intended effective date of termination.

(2) HCFA may approve the termination date proposed by the HCPP, or set a different date no later than 6 months after that date. HCFA 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 HCFA 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 HCFA. HCFA 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 HCFA. HCFA 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 HCFA an annual operating budget and enrollment forecast, in the form and detail specified by HCFA, 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 HCFA 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 HCFA. 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, HCFA 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 HCFA 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.* HCFA and an HCPP must make a final settlement, and payment of amounts due either to the HCPP or to HCFA, 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 HCFA a cost report and supporting documents in the form and detail specified by HCFA, 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 HCFA.

(3) *Extension of time to submit cost report.* HCFA 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, HCFA 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, HCFA 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. HCFA sends to the HCPP a notice of

the amount of reimbursement by the Medicare program. This notice—

(1) Explains HCFA'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 HCFA's determination, HCFA 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 HCFA.

(2) If the HCPP does not pay HCFA within 30 days of HCFA's determination of any amounts the HCPP owes HCFA, HCFA 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 HCFA 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, HCFA will make an interim settlement by estimating the amount payable to the HCPP.

(2) HCFA or the HCPP will make payment within 30 days of HCFA'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 subpart R of 20 CFR part 404 dealing with representation of parties under title II of the Act are, unless otherwise provided, also applicable.

[59 FR 59943, Nov. 21, 1994]

§ 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 HCFA.

[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]

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 physician who—

(a) Is a doctor of medicine or osteopathy; and

(b) 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]

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.

(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]

§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) HCFA 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. HCFA 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) HCFA 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 HCFA, 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 provided in paragraphs (d) (2) and (3) of this section, the hospice must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference)[1] that are applicable to hospices.

(2) In consideration of a recommendation by the State survey agency, HCFA 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) Any hospice that, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard, as long as the hospice continues to remain in compliance with that edition of the Life Safety Code.

[1] See footnote to § 405.1134(a) of this chapter.

(4) Any facility of two or more stories that is not of fire resistive construction and is participating on the basis of a waiver of construction type or height, may not house blind, nonambulatory, or physically handicapped patients above the street-level floor unless the facility—

(i) Is one of the following construction types (as defined in the Life Safety Code):

(A) Type II (1, 1, 1)—protected noncombustible.

(B) Fully sprinklered Type II (0, 0, 0)—non-combustible.

(C) Fully sprinklered Type III (2, 1, 1)—protected ordinary.

(D) Fully sprinklered Type V (1, 1, 1)—protected wood frame; or

(ii) Achieves a passing score on the Fire Safety Evaluation System (FSES).

(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, HCFA 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]

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]

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) HCFA 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 HCFA 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) The intermediary reimburses the hospice at the appropriate payment amount for each day for which an eligible Medicare beneficiary is under the hospice's care.

(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]

§ 418.304 Payment for physician services.

(a) The following services performed by hospice physicians 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.

§ 418.306 Determination of payment rates.

(a) *Applicability.* HCFA 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 by intermediary.* The payment rates established by HCFA are adjusted by the intermediary to reflect local differences in wages.

(d) *Federal Register notices.* HCFA 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]

§ 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 HCFA 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 HCFA 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 HCFA in accordance with § 418.306 are not reduced when the individual is liable for coinsurance payments. Instead, when establishing the payment rates, HCFA offsets the estimated cost of services by an estimate of average coinsurance amounts hospices collect.

[56 FR 26919, June 12, 1991]

PART 420—PROGRAM INTEGRITY: MEDICARE

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: 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 HCFA 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 HCFA's acceptance of a provider agreement or issuance or reissuance of a supplier billing number, or at any time upon written request by HCFA, the provider or part B supplier must furnish HCFA 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.* HCFA 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, HCFA 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. HCFA 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.* HCFA 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 HCFA, 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 HCFA 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 HCFA 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) HCFA 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) HCFA 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, HCFA 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 HCFA 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.

PART 421—INTERMEDIARIES AND CARRIERS

Subpart A—Scope, Definitions, and General Provisions

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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 HCFA 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 HCFA 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 HCFA 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.* HCFA 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 HCFA 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 HCFA and HCFA is the real party of interest in any litigation involving the administration of the program.

(c) *Use of intermediaries to perform carrier functions.* HCFA 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, HCFA 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, HCFA 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 HCFA 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 PRO determinations when they are services for which the PRO has assumed review responsibility under its contract with HCFA.

(2) The intermediary takes appropriate action to reject or adjust the claim if—

(i) The intermediary or the PRO 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 HCFA 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 HCFA for the reconsideration of its determinations to deny payments to an individual or to the provider that furnished services to the individual. The PRO performs reconsideration of cases in which it made a determination subject to reconsideration.

(g) *Information and reports.* The intermediary must furnish to HCFA any information and reports that HCFA 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 HCFA.

(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 HCFA (subject to the provisions of paragraph (b) of this section); or

(2) Through an intermediary, when both HCFA and the intermediary consent.

(b) Whenever HCFA determines it appropriate, it may contract with any organization (including an intermediary with which HCFA 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 HCFA of its nonconcurrence with the nomination.

(3) The nomination must be made in writing, to HCFA, 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 HCFA already has an agreement, if HCFA and the intermediary agree to it (see § 421.106); or

(3) Elect to receive payment from HCFA as provided in § 421.103.

(c) HCFA 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) HCFA 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 HCFA 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 HCFA.

[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 HCFA, by—

(1) Giving HCFA 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 HCFA 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, HCFA 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. HCFA 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 HCFA 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 HCFA 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 HCFA 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 HCFA.

HCFA 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 HCFA 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, HCFA may designate a particular intermediary to serve a class of providers nationwide or in any geographic area it defines. HCFA 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, HCFA 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 HCFA to contract with any organization for the purpose of making payments to any provider that elects to receive payment directly from HCFA.

(b) HCFA 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 HCFA'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 HCFA.

(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 HCFA.

(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 HCFA 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 HCFA Regional Office to receive payment through an alternative regional intermediary designated by HCFA.

(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 HCFA 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, HCFA 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 HCFA 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, HCFA 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.* HCFA 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, HCFA 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), HCFA 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, HCFA 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, HCFA publishes the performance standards as part of the FEDERAL REGISTER notice describing the performance criteria issued under § 421.120(c). HCFA may not necessarily publish the criteria and standards every year. HCFA 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 HCFA, 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, HCFA 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 HCFA 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 HCFA 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) HCFA 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 HCFA 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 HCFA 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 HCFA 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 PRO determinations when they are services for which the PRO has assumed review responsibility under its contract with HCFA.

(2) The carrier takes appropriate action to reject or adjust the claim if—

(i) The carrier or the PRO 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 HCFA any information and reports that HCFA requests in order to carry out HCFA'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 HCFA 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, Jun. 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, HCFA 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.* HCFA bases the performance criteria and standards on—

(1) Nationwide carrier experience;

(2) Changes in carrier operations due to fiscal constraints; and

(3) HCFA'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, HCFA publishes the performance criteria and standards as a notice in the FEDERAL REGISTER. HCFA may not necessarily publish the criteria and standards every year. HCFA 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, HCFA 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 HCFA 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 HCFA 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) and 1834(h) of the Act which authorize the Secretary to designate one or more carriers by specific regions to process claims for durable medical equipment, prosthetic devices, prosthetics, orthotics and other supplies (DMEPOS). This authority has been delegated to HCFA.

(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 HCFA.

(c) *Region designation*. The boundaries of the four regions for processing claims described in paragraph (b) of this section coincide with the boundaries of 1 or more sectors or areas designated for the Common Working File. These four regions contain the following States and territories: Region A: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, and Delaware. Region B: Maryland, the District of Columbia, Virginia, West Virginia, Ohio, Michigan, Indiana, Illinois, Wiconsin and Minnesota. 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. 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.

(d) *Criteria for designating regional carriers.* HCFA designates regional carriers to achieve a greater degree of effectiveness and efficiency in the administration of the Medicare program as measured by—

(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 HCFA believes to be pertinent.

(e) *Carrier designation*. (1) Each carrier designated a regional carrier is responsible, using the payment rates applicable for the State of residence of a beneficiary, including a qualified Railroad Retirement beneficiary, for processing claims for items listed in paragraph (b) of this section for beneficiaries whose permanent residence is within the area designated in paragraph (c) of this section. 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) The regional carriers designated to process DMEPOS claims (as defined in paragraph (b) of this section) for all Medicare beneficiaries residing in their respective regions (as designated in paragraph (c) of this section), including those entitled under the Railroad Retirement Act, are the following:

(i) The Travelers Insurance Company (Region A), which will be processing claims in Pennsylvania.

(ii) Associated Insurance Companies, Inc.—AdminaStar (Region B), which will be processing claims in Indiana.

(iii) Blue Cross and Blue Shield of South Carolina (doing business as Palmetto Governments Benefits Administrators) (Region C), which will be processing claims in South Carolina.

(iv) Connecticut General Life Insurance Co. (a CIGNA Company) (Region D), which will be processing claims in Tennessee.

(3) Blue Cross and Blue Shield of South Carolina (Palmetto Government Benefits Administrators) has been selected to serve as the National Supplier Clearinghouse and the Statistical Analysis DME regional carrier.

(4) The contracts for the four DME regional carriers will be periodically recompeted. The National Supplier Clearinghouse and Statistical Analysis DME regional carrier do not constitute separate contracts, but are contract amendments to one of the DME regional carrier contracts. The National Supplier Clearinghouse and Statistical Analysis DME regional carrier contract amendments will also be periodically recompeted.

(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]

§ 421.212 Railroad Retirement Board contracts.

In accordance with this subpart C, the Railroad Retirement Board contracts with DMEPOS regional carriers designated by HCFA, 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 HCFA 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 HCFA'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) HCFA determines that the prompt payment interest provision specified in section 1842(c) of the Act is insufficient to make a claimant whole.

(3) HCFA 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 HCFA.

(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 HCFA 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 HCFA.* (1) In accordance with the provisions of this section, HCFA may determine that circumstances warrant the issuance of advance payments to all affected suppliers furnishing Part B services. HCFA 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, HCFA 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 HCFA'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]

EFFECTIVE DATE NOTE: At 61 FR 49275, Sept. 19, 1996, §421.214 was added, effective Oct. 21, 1996.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

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424.352 Intermediary and carrier checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.

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.

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]

§ 424.3 Definitions.

As used in this part, unless the context indicates otherwise—

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]

§ 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 PRO 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 PRO 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 HCFA 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 PRO 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 HCFA 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 HCFA 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 RPCH services.

(a) *Content of certification.* Medicare Part A pays for inpatient RPCH services only if a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 72 hours after admission to the RPCH.

(b) *Timing of certification.* Certification is required no later than 1 day before the date on which the claim for payment for the inpatient RPCH services is submitted.

[58 FR 30671, May 26, 1993, as amended at 60 FR 45850, Sept. 1, 1995]

§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 a SNF, or a hospital or RPCH 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.* (i) Posthospital SNF care is or was required because 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 a SNF or a swing-bed hospital on an inpatient basis; and

(ii) 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.

(2) *Special requirement: 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, *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.

(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]

§ 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 2 months, preferably at the time the plan is reviewed, and must be signed by the physician who reviews the plan.

(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) *Limitations on the performance of certification and plan of treatment functions.* (1) *Basic rule.* Beginning November 26, 1982, and except as provided in paragraph (e) of this section, 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 significant ownership interest in, or a significant financial or contractual relationship with, that HHA.

(2) *Significant ownership interest.* A physician is considered to have a significant ownership interest in an HHA if he or she—

(i) Has a direct or indirect ownership interest of 5 percent or more in the capital, the stock, or the profits of the home health agency; or

(ii) Has an ownership interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation that is secured by the agency, if that interest equals 5 percent or more of the agency's assets.

(3) *Significant financial or contractual relationship.* Beginning November 26, 1982, a physician is considered to have a significant financial or contractual relationship with an HHA if he or she—

(i) Receives any compensation as an officer or director of the HHA; or

(ii) Has direct or indirect business transactions with the HHA that, in any fiscal year, amount to more than $25,000 or 5 percent of the agency's total operating expenses, whichever is less. Business transactions means contracts, agreements, purchase orders, or leases to obtain services, supplies, equipment, and space and, after August 29, 1986, salaried employment.

(4) *Exemption of uncompensated officer or director.* A physician who serves as an uncompensated officer or director of an HHA is not precluded from performing physician certification and plan of treatment functions for that HHA.

(e) *Exceptions to limitations.* (1) *Exceptions for governmental entities.* The limitations of paragraph (d) of this section do not apply to an HHA that is operated by a Federal, State, or local governmental authority.

(2) *Exception for sole community HHAs.* The limitations of paragraph (d) of this section do not apply on or after the date on which the HHA is classified as a sole community HHA in accordance with paragraphs (f) and (g) of this section.

(f) *Procedures for classification as a sole community HHA.* (1) The HHA must submit to its intermediary a request for classification, showing that it meets the conditions of paragraph (g) of this section.

(2) The intermediary reviews the request and sends the request, with its recommendations, to HCFA.

(3) HCFA reviews the request and the intermediary's recommendation and forwards its approval or disapproval to the intermediary

(4) An approved classification as sole community HHA remains in effect without need for reapproval unless there is a change in the circumstances

[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.

under which the classification was approved.

(g) *Basis for classification as a sole community HHA.* HCFA approves a classification as a sole community HHA only if the HHA designates a particular area and shows that no other HHA provides services within that area.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, Mar. 1, 1991]

§ 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 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. (For physical therapy services furnished after July 17, 1984, the physician may be a doctor of podiatric medicine, provided the services are consistent with the functions he or she is authorized to perform under State law.)

(iii) The services were furnished under a plan of treatment that meets the requirements of § 424.25.

(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, the certification must be signed by that physician.

(ii) If the plan of treatment is established by a physical therapist or speech pathologist, the certification must be signed by a physician 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 who reviews the plan of treatment.

(ii) *Content.* The continuing need for physical therapy or speech pathology services and an estimate of how much longer the services will be needed.

(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.

(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 who has knowledge of the case.

(3) *Timing.* The physician 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]

§ 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 HCFA in accordance with HCFA instructions.

(2) A claim for physician services must include appropriate diagnostic coding 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.

(b) The prescribed forms for claims are the following:

HCFA–1450—Uniform Institutional Provider Bill. (This form is for institutional provider billing for Medicare inpatient, outpatient and home health services.)

HCFA–1490S—Request for Medicare payment. (For use by a patient to request payment for medical expenses.)

HCFA–1490U—Request for Medicare Payment by Organization. (For use by an organization requesting payment for medical services.)

HCFA–1491—Request for Medicare Payment-Ambulance. (For use by an organization requesting payment for ambulance services.)

HCFA–1500—Health Insurance Claim Form. (For use by physicians and other suppliers to request payment for medical services.)

HCFA–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 HCFA–1450 and HCFA–1500, all claims forms prescribed for use in the Medicare program are distributed free-of-charge to the public, institutions, or organizations. The HCFA–1450 and HCFA–1500 may be obtained only by commercial purchase. All other claims forms can be obtained upon request from HCFA or any Social Security branch or district office, or from Medicare intermediaries or carriers. The HCFA–1490S is also available at local Social Security Offices.

[53 FR 6639, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 59 FR 10299, Mar. 4, 1994]

§ 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 HCFA 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 HCFA 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, HCFA 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 HCFA 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.

§ 424.45 What constitutes a claim for purposes of meeting the time limits.

A written statement of intent to claim Medicare benefits constitutes a claim if—

(a) The statement is filed with HCFA or any carrier or intermediary within the time limits specified in § 424.44;

(b) The statement indicates the intent to claim Medicare payment for specified services furnished to an identified beneficiary; and

(c) A claim that meets the requirements of § 424.32(a) is filed within 6 months after the month in which the intermediary or carrier, as appropriate, advises the claimant to file that claim.

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 the carrier determines to be the reasonable 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 reasonable charge.

(ii) To collect only the amount of the unmet deductible, plus 20 percent of the difference between the reasonable charge and the unmet deductible for those services for which Medicare pays 80 percent of that difference.

(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.

§ 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 numbers.

(a) *Definitions.* As used in this section ''DMEPOS'' is the acronym for durable medical equipment, prosthetics, orthotics and supplies. A ''supplier'' is an entity or individual, including a physician or 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.

(b) Medicare pays for items furnished by a supplier with a billing number to the—

(1) Supplier 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;

(2) Beneficiary, if the supplier does not accept assignment; or

(3) Partly to the beneficiary and partly to the supplier, if the supplier accepts assignment of the bill, as described in § 424.56.

(c) Medicare does not issue a billing number to a supplier that submits claims for items listed in § 421.210(b) of this subchapter until that supplier meets, and certifies that it meets, the following standards. The supplier—

(1) In response to orders which it receives, fills those orders from its own inventory or inventory in other companies with which it has contracted to fill such orders or fabricates or fits items for sale from supplies it buys under a contract;

(2) Is responsible for delivery of Medicare covered items to Medicare beneficiaries;

(3) Honors all warranties express and implied under applicable State law;

(4) Answers any questions or complaints a beneficiary has about the item or use of the item that was sold or rented to him or her, and refers beneficiaries with Medicare questions to the appropriate carrier;

(5) Maintains and repairs directly or through a service contract with another company, items it has rented to beneficiaries;

(6) Accepts returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and/or sold) from beneficiaries;

(7) Discloses consumer information to each beneficiary with whom it does business which consists of the supplier standards to which it must conform;

(8) Complies with the disclosure provisions in § 420.206;

(9) Complies with all applicable State and Federal licensure and regulatory requirements;

(10) Maintains a physical facility on an appropriate site; and

(11) Has proof of appropriate liability insurance.

(d) If a supplier is found not to meet the standards in paragraph (c) of this section, its billing number is revoked, effective 15 days after the entity is sent notice of the revocation. A billing number may be issued, with the concurrence of HCFA, when a supplier has successfully completed a corrective action plan rectifying past violations of the supplier standards and provided sufficient assurance that it will comply with the supplier standards in the future. Corrective action includes repayment of monies due to beneficiaries and Medicare, and honoring applicable warranties.

(e) Suppliers must renew their applications for a billing number 3 years after the billing numbers are first reissued, except for the first reissuance process, as follows: suppliers must renew applications for supplier numbers 2 years after initial issuance of billing numbers for one third of all suppliers. Another one third of suppliers must reapply 3 years after initial issuance. The last third of suppliers must reapply 4 years after initial issuance. Thereafter, each supplier must reapply 3 years after its last number is issued, unless no claim for an item furnished by a supplier has been submitted for four consecutive quarters, in which case the supplier must submit a new request for another billing number.

(f) Suppliers are required to have complaint resolution protocols to address beneficiary complaints which relate to the supplier standards in paragraph (c) of this section and to keep written complaints and related correspondence, and any notes of actions taken in response to written or oral complaints. Failure to maintain such information may be considered evidence that supplier standards have not been met. If a carrier determines that a supplier is not satisfactorily responding to one or more beneficiary complaints, the carrier may require that a supplier maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives: The name, address, telephone number and health insurance claim number of the complaint, a summary of the complaint

and the date it was made; the name of the person taking the complaint, a summary of any actions taken to resolve the complaint; and, if an investigation was not conducted, the name of the person making the decision and the reason for the decision.

[57 FR 27308, June 18, 1992, as amended at 60 FR 63444, Dec. 11, 1995]

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 HCFA-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 HCFA-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 HCFA-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 HCFA 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 HCFA 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.

Health care delivery system or *system* means a public or private organization for delivering health services. The term includes, but is not limited to, clinics and health care prepayment plans.

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.

§ 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.

HCFA 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 HCFA 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.

(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 a facility.* Medicare may pay the facility in which the services were furnished if there is a contractual arrangement between the facility and the supplier under which the facility bills for the supplier's services.

(3) *Payment to health care delivery system.* Medicare may pay a health care delivery system if there is a contractual arrangement between the system and the supplier under which the system bills for the supplier's services.

(4) *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.

(5) *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.

(6) *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, facility, or system.* An employer, facility, or system that may receive payment under paragraph (b)(1), (b)(2), or (b)(3) of this section will itself be considered

the supplier of those services for purposes of the rules of subparts C, D, and E of this part.

[53 FR 6634, Mar. 2, 1988, as amended at 54 FR 4027, Jan. 27, 1989]

§ 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.* HCFA may revoke the right of a supplier or other party to receive Medicare payments if the supplier or other party, after warning by HCFA 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 HCFA 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. HCFA 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.* HCFA 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 HCFA 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, ''HCFA'' 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, HCFA'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 HCFA's final determination.

(b) *Notice of final determination.* HCFA 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 HCFA on the matter.

(2) A final determination to revoke remains in effect until HCFA 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 HCFA, signed by an authorized official of the hospital, and

either received by HCFA, or postmarked, before the close of the calendar year of election.

(c) *Acceptance and effective date of election.* If HCFA accepts the election statement, the election is effective as of the earliest day of the calendar year of election from which HCFA 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 HCFA has notified a hospital that it no longer qualifies to receive reimbursement for a calendar year, HCFA will not accept another election statement from that hospital until HCFA 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) HCFA 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.* HCFA 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, HCFA 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.* HCFA 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 HCFA 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 HCFA 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 HCFA 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 § 410.140 of this chapter.

[53 FR 6646, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988]

§ 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 HCFA 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 HCFA 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 HCFA.

(2) *Action by HCFA.* HCFA 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]

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.

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(Revised as of October 1, 1996)

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.

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	42 CFR
American Hospital Association Available from: Health Care Financing Administration, 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 Available from Engineering Societies' Library, 345 E. 47th St., New York, NY 10017	
ANSI A117.1–1971 Specifications for Making Buildings and Facilities Accessible to and Usable by Physically Handicapped People.	405.1134(c)
American Psychiatric Association 1700 18th St. NW., Washington, DC 20009	
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)

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Redesignation Table I

At 51 FR 22040, June 17, 1986, §§405.1011—405.1042 (subpart J), formerly appearing in title 42, part 405, were redesignated as part 482 of title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.1011	482.2
405.1020	482.11
405.1021(a)–(d)	482.12
405.1021(e)	482.12(a)
405.1021(f) & (g)	482.12(b)
405.1021(h)	482.12(c)
405.1021(i)	482.41
405.1021(j)	482.12(d)
405.1022	482.41 and 482.42
405.1023	482.22
405.1024 except (d)	482.23
405.1024(d)	482.51
405.1025	482.28
405.1026	482.24
405.1027	482.25
405.1028	482.27
405.1029	482.26
405.1030	Deleted
405.1031(a)	482.51
405.1031(b)	482.52
405.1031(c)	Deleted as duplicative of 482.22
405.1031(d)	482.56
405.1032	482.54
405.1033	482.12(f)
405.1034	Deleted. Provision included as part of 482.21(b)
405.1035	482.30
405.1036	482.60
405.1037	482.61
405.1038	482.62
405.1039	Deleted. Provisions removed by law.
405.1040	Deleted. Provisions removed by law.
405.1041	482.66
405.1042	482.30

Redesignation Table II

At 51 FR 34790, Sept. 30, 1986, certain sections of regulations formerly appearing in title 42, part 405, subpart D, were redesignated as part 413 of title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.401	413.1
405.402	413.5
405.403	413.50
405.405	413.60
405.406	413.20
405.414	413.130
405.415	413.134
405.416	413.139
405.417	413.144
405.418	413.149
405.419	413.153
405.420	413.80
405.421	413.85
405.422	413.90
405.424	413.94
405.425	413.98
405.426	413.102
405.427	413.17
405.429	413.157

Old section	New section
405.432	413.106
405.433	413.110
405.434	413.114
405.435	413.161
405.436	413.178
405.438	Deleted
405.439	413.170
405.440	Deleted
405.441	413.174
405.451	413.9
405.452	413.53
405.453	413.24
405.454	413.64
405.455	413.13
405.456	413.74
405.457	413.56
405.460	413.30
405.461	413.35
405.463	413.40

Redesignation Table III

At 51 FR 34764, Sept. 30, 1986, a document was published by the Department of Health and Human Services which established in title 42 a new chapter V, Office of Inspector General—Health Care, consisting of parts 1001 through 1004. This document also removed part 101 from title 45. A second document at 51 FR 34786, Sept. 30, 1986 amended title 42, parts 412, 420, 455, 466, 474, and 489. The following derivation table identifies the sections of 42 CFR chapter IV and 45 CFR subtitle A from which the new 42 CFR chapter V derives its content.

Old section	New section
42 CFR Chapter IV	
420.1	1001.1
420.2	1001.2
420.3	1001.3
420.100	1001.100
420.101	1001.101
420.102	1001.102
420.103	1001.103
420.105	1001.105
420.107	1001.107
420.109	1001.109
420.114	1001.114
420.115	1001.115
420.122	1001.122
420.123	1001.123
420.124	1001.124
420.125	1001.125
420.126	1001.126
420.128	1001.128
420.130	1001.130
420.132	1001.132
420.134	1001.134
420.136	1001.136
489.54	1001.201
489.55	1001.211
489.57	1001.221
412.48(c), (d), and (e)	1001.301
455.1	1002.1
455.2	1002.2
455.106	1002.3
455.200	1002.200
455.203	1002.203
455.204	1002.204
455.205	1002.205
455.206	1002.206
455.207	1002.207
455.208	1002.208
455.210	1002.210
455.211	1002.211
455.212	1002.212
455.213	1002.213
455.214	1002.214
455.230	1002.230
455.234	1002.232
455.234	1002.234–1002.321
455.300	1002.301
45 CFR Subtitle A	
101.100	1003.100
101.101	1003.101
101.102	1003.102
101.103	1003.103
101.104	1003.104
101.105	1003.105
101.106	1003.106
101.107	1003.107
101.108	1003.108
101.109	1003.109
101.110	1003.110
101.111	1003.111
101.112	1003.112
101.113	1003.113
101.114	1003.114
101.115	1003.115
101.116	1003.116
101.117	1003.117
101.118	1003.118
101.119	1003.119
101.120	1003.120
101.122	1003.122
101.123	1003.123
101.124	1003.124
101.125	1003.125
101.126	1003.126
101.127	1003.127
101.128	1003.128
101.129	1003.129
101.130	1003.130
101.131	1003.131
101.132	1003.132
101.133	1003.133
42 CFR Chapter IV	
474.0	1004.1
474.30	1004.10
474.32	1004.20
474.34	1004.30
474.36	1004.40
474.38	1004.50
474.39	1004.60
474.40	1004.70
474.41	1004.80
474.42	1004.90
474.52	1004.100
474.54	1004.110
474.56	1004.120
474.58	1004.130

Redesignation Table IV

At 51 FR 41335, Nov. 14, 1986, certain sections of regulations formerly appearing in title 42, part 405, subpart B were redesignated as part 410 of title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.230	410.150
405.231(a)	410.10(a), 410.20
405.231(b)	410.10(b), 410.26
405.231(c)	410.10(c), 410.27
405.231(d)	410.10(f), 410.32
405.231(e)	410.10(g), 410.34
405.231(f)	410.10(h), 410.36(a)
405.231(g)	410.10(i), 410.38
405.231(h)	410.10(h), 410.36(b)
405.231(i)	410.10(h), 410.36(c)
405.231(j)	410.10(j), 410.40
405.231(k)	410.10(d), 410.28
405.231(l)	410.10(m), 410.60
405.231(m)	410.10(m), 410.62
405.231(n)	410.10(k), 410.45
405.231(o)	410.10(l), 410.50
405.231(p)	410.10(l), 410.52
405.231(a)	410.10(o), 410.55
405.232(b)	Removed as outdated.
405.232(b)	410.32
405.232(c)	410.29
405.232(d)	410.28
405.232(e)	410.60
405.232(f), (g), and (h)	410.32 and 410.34
405.232(i)	410.40
405.232(j)	410.62
405.232a(a)(1)	410.20
405.232a(a)(2)	410.20(b) and 410.24
405.232a(a)(3)	410.20(b) and 410.25
405.232a(a)(4)	410.20(b) and 410.23
405.232a(a)(5)	410.20(b) and 410.22
405.232a(b)	410.14
405.232b	410.22
405.232c	410.23
405.233	Removed as inconsistent with current law which no longer limits the home health visits.
405.234	Removed as duplicative of §409.42(b) and (d)
405.235	Removed as duplicative of §409.42(e)
405.236	Removed as duplicative of 409.40
405.237	Removed as duplicative of 409.41
405.238	Removed as duplicative of 409.43
405.239	Removed as inconsistent with current law which no longer limits the number of home health visits.
405.240	410.152
405.241	410.152(a)(2)(iii)
405.243	410.155
405.244a	410.152(a)(1)(i)
405.244(b)	410.152(a)(1)(ii)
405.244(c)	Removed as inconsistent with current law which no longer provides for 100 percent payment for radiology and pathology services.
405.244–1(a)	410.163
405.244–1(b)	410.152(i)(1)
405.244–1(c)	410.152(i)(2)
405.245	410.160
405.246	410.161
405.249	410.168
405.250	410.170
405.250–2	410.165
405.251	Removed as duplicative of Subpart P of Part 405.
405.252	410.175
405.260	410.100
405.261	410.102
405.262	410.105

Redesignation Table V

At 52 FR 22446, June 12, 1987, certain sections of regulations appearing in title 42, part 405, subparts F and O were redesignated as part 498 of title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.640	498.20(a)(2)
405.685	405.1902(b)
405.1501(a)	Removed as duplicative of § 405.1502.
405.1501(b), (c), and (e)	498.5
405.1501(d)	498.3(e)
405.1502	498.3(b)
405.1503	498.20(a)
405.1504	498.20(b)
405.1505	498.3(c)
405.1510	498.22(a)
405.1511(a)	498.22(c)
405.1511(b)	498.22(b)
405.1512	498.22(b)(2)
405.1513	498.23
405.1514	498.24
405.1515	498.24
405.1516	498.25(a)
405.1517	498.25(b)
405.1518	498.22(d)
405.1519	498.30
405.1520	498.32(a)
405.1521	498.32(b)
405.1530	Removed as duplicative of § 405.1531.
405.1531	498.40
405.1532	498.42
405.1533	498.44
405.1534	498.45
405.1535	498.47
405.1536	498.48
405.1537	498.49
405.1538	498.50
405.1539	498.50
405.1540	498.52
405.1541	498.53
405.1542	498.56
405.1543	498.54
405.1544	498.58
405.1545	498.60
405.1546	498.61
405.1547	498.62
405.1548	498.63
405.1549	498.64
405.1550	498.66
405.1551	498.68
405.1552	498.69
405.1553	498.70
405.1554	498.71
405.1555	498.71
405.1556	498.72
405.1557	498.74
405.1558	498.74
405.1559	498.76
405.1560	498.78
405.1561	498.80
405.1562	498.82
405.1563	498.83
405.1564	498.85
405.1565	498.86
405.1566	498.88
405.1567	498.90
405.1568	498.83
405.1569	498.95
405.1570	498.100
405.1571	498.102
405.1572 and 405.1571(c)	498.103
405.1590	498.10
405.1591	498.11
405.1592	498.13
405.1593	498.15
405.1594	498.11(b)
405.1595	498.17.

Redesignation Table VI

At 52 FR 36746, Sept. 30, 1987, regulations appearing in title 42, part 110 were redesignated as part 417, subpart A of title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
110.101	417.100
110.102	417.101
110.103	417.102
110.104	417.103
110.105	417.104
110.106	417.105
110.107	417.106
110.108	417.107
110.109	417.108
110.110	417.109
110.201	417.110
110.202	417.111
110.203	417.112
110.204	417.113
110.205	417.114
110.206	417.115
110.207	417.116
110.208	417.117
110.209	417.118
110.210	417.119
110.401	417.120
110.402	417.121
110.403	417.122
110.404	417.123
110.405	417.124
110.406	417.125
110.407	417.126
110.501	417.130
110.502	417.131
110.503	417.132
110.504	417.133
110.505	417.134
110.506	417.135
110.507	417.136
110.508	417.137
110.601	417.140
110.602	417.141
110.603	417.142
110.604	417.143
110.605	417.144
110.801	417.150
110.802	417.151
110.803	417.152
110.804	417.153
110.805	417.154
110.806	417.155
110.807	417.156
110.808	417.157
110.809	417.158
110.810	417.159
110.901	417.160
110.902	417.161
110.903	417.162
110.904	417.163
110.905	417.164
110.906	417.165
110.907	417.166
110.1001	417.170
110.1002	417.171
110.1003	417.172
110.1004	417.173
110.1005	417.174
110.1006	417.175
110.1007	417.176
110.1008	417.177
110.1009	417.178
110.1010	417.179
110.1011	417.180

Redesignation Table VII

At 53 FR 6632, Mar. 2, 1988, §§405.100—405.192 (subpart A) and 405.1625—405.1697 (subpart P), formerly appearing in title 42, part 405, were redesignated as part 424 of title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.100	424.10
405.150	409.100 and 424.51
405.152(a) (1) and (2)	424.101
405.152(a)(3)	424.103 Introductory text
405.152(a)(4)	Removed as duplicative of 405.152(c)
405.152(a)(5)	424.103(a)(2)
405.152(a)(6)	Removed as duplicative of 405.1660
405.152(a)(7)	424.103(a)(1)
405.152(a)(8)	424.103(b)
405.152(b)	424.101
405.152 (c), (d), and (e)	424.104
405.153(a)	424.121(a)
405.153(a)(1)	424.122(a)
405.153(a)(2)	424.122(b)
405.153(a)(3)	424.122(d) and 424.123 (c) and (d)
405.153(b)	424.121(a)
405.153(b)(1)	424.123(a)
405.153(b)(2)	424.123(b)
405.153(b)(3)	424.123(c)
405.153(c)(1)	424.123(d) and 424.126
405.153(c)(2)	424.127
405.157	424.103(a) and 424.109(a)
405.158	424.109(b)
405.160(a) (1) and (2)	424.5
405.160(a)(3)	424.7
405.160(b)(1)	424.5(a)(5)
405.160(b)(2)	424.5(a)(4), 424.11, 424.14
405.160(b)(3)	424.14
405.160(b)(4)	424.7
405.160(c)	Removed as no longer pertinent. Inpatient services in TB hospitals are no longer included in the statute
405.162	424.7(a)
405.163	424.7(b)
405.165(a)	424.5(a)(5)
405.165(b)	424.5(a)(4), 424.11, 424.20
405.165(c)	424.7
405.166	424.7(a)
405.167	424.7(b)
405.170(a)	424.5(a)(5)
405.170(b)	424.5(a)(4), 424.11, 424.22
405.170(c)	424.5(a)(1)
405.191(a)	424.103(a)(4)
405.191(b)	Removed as unnecessary
405.191(b)(1)	424.103(b)
405.191(b)(2)	424.103(b)
405.191(b)(3)	424.103(a)(3)
405.191(b)(4) 1st sentence	Removed as poor example
405.191(b)(4) 2nd sentence	424.102(a)
405.191(b)(5)	424.102(b)
405.192(a)	424.106(a)
405.192(b)	Removed as unnecessary
405.192(b) (1)–(3)	424.106(b)
405.192(b)(4)	424.106(c)
405.192(c)	424.106(d)
405.192(d)(1)	Removed as inconsistent with definition of emergency
405.192(d)(2)	Removed as redundant with 405.192(c)
405.1625(a)	424.10(a)
405.1625(b)	424.11(a)
405.1625(c)	424.11(b)
405.1625(d)	424.11(c)
405.1625(e)	424.11(d)
405.1627 (a)(1)–(a)(3)	424.13(a)
405.1627(b)	424.13(b)
405.1627(c)	424.13(c)
405.1627(d)	424.13(d)
405.1627(e)(1)	424.13(d)
405.1627(e)(2)	424.13(e)
405.1627(e)(3)	424.13(f)
405.1627(e)(4)	424.13(g)
405.1629 Undesignated portion.	424.14 (a) and (d)
405.1629 (a) and (b)	424.14 (b) and (c)
405.1629(c)	Removed as no longer pertinent. (See comment on §405.160(c))
405.1630	424.16
405.1632(a)	424.20, Introductory statement
405.1632(b)	424.20(a)
405.1632(c)	424.20(b)
405.1632(d)	424.20(c)
405.1632(e) (1) and (2)	424.20(d)
405.1632(e)(3)	424.20(f)
405.1632(e)(4)	424.20(g)
405.1632(f)	424.20(e)
405.1633	424.22
405.1634(a)(1)	424.24(a)
405.1634(a)(2)	424.24(c)(4)
405.1634(a)(3)	Removed as duplicative of 405.1625(c)
405.1634(a)(4)	424.24(c)(3)
405.1634(a)(5)	424.24(c)(2)
405.1634(b)	424.24(c)(1) and 424.25
405.1634(c)	424.24(d)
405.1635	424.27
405.1660 (a) and (b)	Removed as duplicative of other content
405.1660(c)	424.5(a)(5)
405.1662(a) 1st sentence	405.207 and 406.7
405.1662(a) 2nd and 3rd sentences.	424.32(a)
405.1662(a) last sentence	Removed as unnecessary
405.1662(b) list of forms	405.207 and 406.7
405.1662(b) narrative	Removed as duplicative of 405.205 and 406.6

Old section	New section
405.1662(c)	424.32(b)
405.1662(d)	405.207, 406.7, and 424.32(c)
405.1663 Undesignated portion.	424.5(a)(5)
405.1663 (a) and (c)	424.40(b)(1)
405.1663 (b) and (d)	424.40(b)(2)
405.1664	424.36 and 424.37(b)
405.1665	424.37(a)
405.1666	424.36
405.1667(a)	424.32
405.1667(b) (1) and (2)	424.44
405.1667(b)(3)	424.45
405.1667(c)	Removed as outdated
405.1668(a)	424.70
405.1668 (b) and (c)	424.73
405.1668(d)	424.74
405.1672 (a) and (b)	424.53
405.1672(c)	424.34(a)
405.1672(d)	424.54
405.1672 (e) and (f)	424.73(b), 424.80(b), 424.86(b)
405.1674	424.34
405.1675(a)(1)	424.55
405.1675(a)(2)	424.56
405.1675(b)	424.80(c)
405.1678	Removed as duplicative of 405.1675
405.1679	424.36
405.1680(a)	424.70(b)
405.1680(b)	424.71
405.1680(c)	424.80(a)
405.1680(d)	424.80(b)
405.1681 (a)–(h)	424.82
405.1681 (i) and (j)	424.83
405.1681 (k) and (l)	424.84
405.1682(a)	424.71
405.1682(b)	424.90(a)
405.1682(c)	424.90(b)
405.1682(d)	424.90(c)
405.1683	424.62
405.1684	424.64
405.1685	424.66 (c) and (d)
405.1686	424.66(a)
405.1692	424.44
405.1693	424.45
405.1694	424.44(c)
405.1695	424.350
405.1696	424.352
405.1697	424.354

Redesignation Table VIII

At 53 FR 23100, June 17, 1988, §§ 405.1901—405.1913 (subpart S), formerly appearing in title 42, part 405, were redesignated as part 488 of title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.1901(a)	488.01
405.1901 (b) and (c)	488.03
405.1901(d)	488.05
405.1901(e)	488.06
405.1901(q)	488.08
405.1902(a)	488.10
405.1902(b)	488.11
405.1902(c)	488.12
405.1902(d)	488.14
405.1903	488.18
405.1904	488.20
405.1905	488.24
405.1906	488.26
405.1907	488.28
405.1908	488.50
405.1909	488.52
405.1910	488.54
405.1911	488.56
405.1912	488.60
	488.100
	488.105
	488.110
	488.115

Redesignation Table IX

At 53 FR 47201, November 22, 1988, §§ 405.201—405.226 (subpart B), formerly appearing in title 42, part 405, were redesignated as part 407 of title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.201	407.1
405.202	407.2
405.205	407.10(a)
405.206	407.10(b)
405.207	407.11
405.210(a)	407.12 and 407.22(b)
405.210(b)	407.17(a) and 407.18
405.210(c)	407.17(b)
405.211	407.12(a)
405.212 (a) & (c)	407.14(a)(1)
405.212(b) [Reserved]	407. Deleted
405.212(d)	407.14(a)(2)
405.212(e)	407.14(b)
405.213	407.12(a) and 407.15
405.214(a) [Reserved]	407. Removed
405.214 (b) & (c)	407. Removed as inconsistent with changes in the law
405.214(d)	407.30
405.215	407.12(b)
405.216	407.20
405.217(a)	407.40(a)
405.217 (b)–(i)	407.40 (c) and (d), 407.42, and 407.43
405.220	407.4(b)
405.221	407.25
405.222	407.47
405.223	407.27, 407, 148, and 407.50
405.226	407.32

Redesignation Table X

At 52 FR 48114, Dec. 18, 1988, regulations appearing in title 42, part 405 were redesignated as part 408 of title 42. The redesignation table was correctly published at 53 FR 4158, Feb. 12, 1988.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.901	408.2
405.902(a)	Deleted as unnecessary
405.902 (a)(1) and (a)(2)	408.20(b)
405.902(b)	408.22
405.902(b)(1)	408.24
Examples	408.26
405.902(c)	408.27
405.903 (a)	408.4(a)
405.903(b), first sentence	408.100
405.903(b), rest of the paragraph.	408.4(b)
405.904, uncoded introduction.	408.6(a)(1) and 408.8(c)
405.904(a)	408.42 and 408.43
405.904(b)	408.44
405.904(c)	408.42
405.904(d)	408.6(c)
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405.928	408.8(b)
405.929	408.8(d)
405.936, text	408.70
405.936, Example	Deleted as unnecessary
405.940(a)	408.80 (a) & (b)
405.940 (b) & (c)	408.80(c)
405.941(a)	408.82(a)
405.941(b)	408.82(b)
405.941(c), first sentence	408.82(e)
405.941(c), rest of paragraph	408.80(b)
405.941(d), first & second sentences.	408.82(c)
405.941(d), rest of paragraph except last sentence.	408.82(d.)
405.941(d), sentence	Deleted as inappropriate in the context of group billing
405.941(e)	408.84(c)
405.941(f), first sentence	408.84(d)
405.941(f), rest of paragraph	408.88(a)
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405.959(a)	408.102(a)
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Redesignation Table XI

At 54 FR 33355, August 14, 1989, §§ 405.1201—405.1230 (subpart L), formerly appearing in title 42, part 405, were redesignated as part 484 of title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.1201	484.1
405.1202	484.2
405.1220	484.10
405.1221	484.12
405.1222	484.14
405.1223	484.16
405.1224	484.30
405.1225	484.32
405.1226	484.34
405.1227	484.36
405.1228	484.48
405.1229	484.52
405.1230	484.38

Redesignation Table XII

At 54 FR 41733 and 41734, October 11, 1989, subpart C of part 405 was amended by removing §§405.308 through 405.344 and a new part 411 was added, to redesignate, revise, and amplify the content removed from subpart C of part 405.

For the convenience of the user, the following table (appearing at 54 FR 41733, Oct. 11, 1989 and corrected at 55 FR 1820, Jan. 19, 1990) shows the relationship of the old §§405.308 through 405.344 and the new part 411.

Old section	New section
405.308(a)	Removed as duplicative of §412.42
405.308(b)	489.34
405.310	411.15
405.310–1	411.2
405.311	411.4
405.311a	411.6
405.311b	411.7
405.312	411.8
405.313	411.9
405.314	411.10
405.315	411.12
405.316	411.40
405.317(a)–(c)	411.30
405.317(d)–(f)	Removed as inconsistent with current policy
405.318	411.43
405.319(a)	Removed for inclusion in instructions
405.319(b)	411.45
405.320 and 321(a)	411.46
405.321(b)	411.47
405.322(a)–(d)	411.50
405.322(e)	411.28
405.323(a)	Removed as outdated
405.323(b)	411.50
405.323(c)(1)	411.53
405.323(c)(2)	411.23
405.323(c)(3) and (4)	411.24
405.323(c)(5)	Removed as meaningless
405.324(a)	411.52
405.324(b)	411.37
405.325	411.30
405.326	411.60
405.327	411.62
405.328(a)–(d)	411.33
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405.329	411.65
405.330	411.400
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405.334	411.404
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405.341	411.72
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405.343	411.35
405.344(a)	411.75
405.344(b)	411.24

Redesignation Table XIII

At 56 FR 51895, October 17, 1991, §§417.110—417.137 (subpart A), formerly appearing in part 405 of title 42, were redesignated as subpart V, part 417 of title 42.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
417.110	417.910
417.111	417.911
417.112	417.912
417.113	417.913
417.114	417.914
417.115	417.915
417.116	417.916
417.117	417.917
417.118	417.918
417.119	417.919
417.120	417.920
417.121	417.921
417.122	417.922
417.123	417.923
417.124	417.924
417.125	417.925
417.126	417.926
417.130	417.930
417.131	417.931
417.132	417.932
417.133	417.933
417.134	417.934
417.135	417.935
417.136	417.936
417.137	417.937

Redesignation Table XIV

At 60 FR 2326, January 9, 1995, §§ 405.1411—405.1416 (subpart N), formerly appearing in title 42, part 405, were redesignated as subpart C, part 486, title 42. Additionally, §§405.1701, 405.1702, and 405.1715—405.1726, formerly appearing in part 405, were redesignated as subpart H, part 485, title 42. Sections 405.1730—405.1737 (subpart Q), formerly appearing in part 405, were redesignated as subpart D, part 486, title 42. And §§411.60 through 411.65 (subpart E) and §§411.70 through 411.75 (subpart F), appearing in part 411 of title 42, were redesignated as subparts F and G of the same part.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section	New section
405.1411	486.100
405.1412	486.102
405.1413	486.104
405.1414	486.106
405.1415	486.108
405.1416	486.110
405.1701	485.701
405.1702, introductory text	Removed
405.1702(a)	485.705(a)
405.1702(b)	485.703(a)
405.1702(c)	485.703(b)
405.1702(d)	485.705(b)
405.1702(e)	485.705(c)
405.1702(f)	485.705(d)
405.1702(g)	485.705(e)
405.1702(h)	485.703(c)
405.1702(i)	485.703(d)
405.1702(j)	485.705(f)
405.1702(k)	485.705(g)
405.1702(l)	485.703(e)
405.1702(m)	485.705(h)
405.1715	485.707
405.1716	485.709
405.1717	485.711
405.1718	485.713
405.1719	485.715
405.1720	485.717
405.1721	485.719
405.1722	485.721
405.1723	485.723
405.1724	485.725
405.1725	485.727
405.1726	485.729
405.1730	486.150
405.1731	486.151
405.1732	486.153
405.1733	486.155
405.1734	486.157
405.1735	486.159
405.1736	486.161
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List of CFR Sections Affected

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For the period before January 1, 1986, see the ''List of CFR Sections Affected, 1949–1963, 1964–1972, and 1973–1985'' published in seven separate volumes.

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405.152 Heading and (a)(5) revised; (c) through (e) added 41336
405.153 (c)(1) amended 34791
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418.202 (c), (f), (g) and (h) amended 41351
420 Authority citation revised 18791
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420.1 Revised 34787
420.2 Removed 34787
420.3 Revised 34787
420.100—420.136 (Subpart B) Authority citation revised 18791
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420.102 Added 18791
420.103 Added 18791
420.105 (a) amended 24490
420.107 (a) amended 24490
420.114 (c) amended 24490
420.134 (e) added 18791
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421.100 (a)(3) amended 43198
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405.583 Technical correction 37769
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405.901—405.964 (Subpart I) Redesignated as Part 408 and revised 48115
405.2100—405.2171 (Subpart U) Authority citation corrected 41532
405.152 (d) corrected 4499
405.212 (e) amended 48123
405.216 Added 48114
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405.226 Amended 48123
405.501—405.580 (Subpart E) Authority citation revised 6152
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405.514 (a) and (k)(2) revised 6152
405.551 (e) revised 6152
405.553 (b)(4) amended 33057
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405.702 Amended 22644
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405.704 (b) introductory text republished; (b)(10) revised 22645
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405.705 (b) amended 22454
405.903 (b) amended 4499
405.1101—405.1137 (Subpart K) Authority citation revised 22645
405.1501—405.1595 (Subpart O) Removed; regulations transferred to new Part 498 22446
405.1901 (e)(6) amended 22454
405.1902 (b) and (c) redesignated as (c) and (d); new (c) heading revised; new (b) and (d) heading added; (b) regulations transferred from 405.685 22446
405.1905 (b) amended 22454
405.2136 (b) introductory text revised (effective date pending) 36934
405.2138 (a) introductory text republished; (a)(3) revised; (a) (4) and (5) added (effective date pending) 36934
405.2139 (a) revised (effective date pending) 36934
405.2140 (b) introductory text and (1) and (c) revised (effective date pending) 36934
405.2150 Added 36935
405.2402 (f) amended 22454
405.2404 (b)(3) amended 22454
408 Redesignated from 405.901—405.964 (Subpart I) and revised 48115
409 Authority citation revised 22645, 27764
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409.42 (b) (2) and (3) corrected 4499
409.60 Revised 22645
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410 Authority citation corrected 29353
410.10 (n) redesignated as (o); new (n) added 27765
410.32 (a)(1) and (b)(3) corrected 4499
410.40 (e)(1) corrected 4499
410.64 Added 27765
410.100 (k)(2) corrected 4499
410.152 (a)(2)(i) and (e)(1) corrected 4499
412 Technical correction 37769
412.1 (a) and (b) amended 33057
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412.2 (d)(5) amended 33057
(c) introductory text and (d) introductory text republished; (c)(5) added; (d)(1) revised 33186
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412.23 (f) revised 33057
412.60 (d) redesignated as (e) and revised; new (d) added 33057
412.63 (c)(4) revised 23834
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412.66 Added 33187
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412.67 Added 33187
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412.68 Added 33188
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412.70 (b), (c) (4) and (5), and (d) (3) and (4) legislative changes 39638

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412.71 (b)(8) amended 33057
412.73 (c)(5) text added; (c)(6) heading removed 33057
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412.82 (c) revised 33189
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412.84 (g) and (i) revised 33189
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412.92 (d) and (e)(1) revised; (f) added 30367
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412.96 (c)(1) introductory text revised 33058
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412.106 (b) and (c)(1) revised; (c) introductory text republished 23834
412.113 (c) amended 33058
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412.118 (c) and (d) introductory text revised 23834
412.125 Introductory text republished; (b) revised 33189
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412.200—412.220 (Subpart K) Added 33058
412.208 (h)(2)(i) corrected 35350
412.214 Added 33190
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413 Correctly designated 26152
413.5 (c) introductory text and (e) revised 21225
(c) introductory text corrected 23398
413.13 (c) redesignated as (c)(1); (c)(2) added 36772
413.30 (f)(7) removed 21225

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413.118 Added 36773
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413.64 (g)(6)(i)) legislative changes 39638
413.118 Added 36773
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413.130 (a) introductory text republished; (a)(8) revised 21225
413.157 Regulations at 52 FR 32921 invalidated 39639
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(b)(2) added; (b)(3) revised; (b)(4) redesignated as (b)(5); new (b)(4) added 32921
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413.161 (a) amended 21226
416.25 (f) amended 22454
416.35 (b)(3) amended 22454
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417.100—417.180 (Subpart A) Redesignated from Part 110; nomenclature changes; subpart designations removed; authority citation added 36746

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417.407 (b) revised.....22322
417.428 (a) introductory text and (b) introductory text republished; (a)(3) and (b)(5) added 8901
417.440 (b)(1) revised; (d) and (e) added 8901
417.450 (a) introductory text revised 8901
417.460 (b) revised 8901
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405.207 Added 6633
405.310 (m)(2) revised.....38526
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405.370 Heading and (a) introductory text revised.....6647
405.502 (a) introductory text republished; (a)(7) and (g) revised; (h) added 26071
405.504 (a)(1) amended.....6648
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405.1316 (f) introductory text republished; (f) (2) and (3) revised.....48647
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405.1702 Introductory text and (d) introductory text and (4)(ii) revised; (f) through (k) redesignated as (g) through (l); new (f) added.....12015
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405.1731 Introductory text and (a) introductory text and (4)(ii) revised; (d) added 12015
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405.1903 Redesignated as 488.18 and (a) and (b) amended.....23100
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405.1911 Redesignated as 488.56 and heading revised and (a) and (b) amended 23100

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405.1912 Redesignated as 488.60 and heading revised, (a) and (b) amended, and nomenclature change 23100
405.1913 Redesignated as 488.64 and nomenclature change 23100
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405.2112 Revised (effective date pending in part) 1620
405.2113 (a) revised 1620
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405.2171 (a) and (e) revised 6548
405.2180—405.2182 Added; eff. 10–19–88 36277
405.2184 Added; eff. 10–19–88 36277
406 Authority citation revised 6633
406.1—406.7 (Subpart A) Heading revised 47202
406.6 (c) introductory text republished; (c) (3) and (4) amended; (c)(5) added 47202
406.7 Added 6633
406.11 Heading revised; (b) introductory text, (b) (1)(ii), and (e)(2) amended 47202
406.12 (c) introductory text revised; (c)(4) redesignated as (c)(5) and republished; new (c)(4) added 47202
406.15 Added 47202
406.21 (a) and (c)(2) revised; (e) added 47203
406.22 (a)(2) and (c) revised; (a)(3) added 47203
406.23 (a) revised; (c) (3), (4) and (5) added 47203
406.25 (b) (1) and (2) amended 47204
407 Added (Regulations transferred from 405.201—405.226 (Subpart B) 47204
408 Redesignation table corrected 4158
408.1 (a) and (b) corrected 4158
408.2 (b) corrected 4159
408.4 (b)(1) corrected 4159
408.24 (a)(6)(ii) and (7)(ii) amended 6648
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409.5 Amended 6648
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409.69 Removed 6633
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409.100—409.102 (Subpart H) Added 6633
410.1 (b) heading and text amended; parenthetical statement added 6648
410.12 (a)(3) amended 6648
410.14 Amended 6648
410.40 (d) amended 6648
410.60 (a)(2) amended 6648
410.62 (a)(2)(iii) amended 6648
410.66 Added 6634
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410.150 (a)(1) and (b) (3) and (4) amended 6648
410.152 (a)(2)(i), (b)(3), and (i)(1)(ii) amended 6648
410.161 (b)(3) amended 6648
410.168 Removed 6634
(b) (6) and (7) and (c)(1) amended 6648
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410.170 (b) (1), (2), and (3) amended 6648
410.175 Revised 6634
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(b) corrected 12945
412 Authority citation revised 1626
412 Addendum corrected 38835
412.2 (c) (1) and (3) amended; (e) introductory text republished; (e)(6) added 38526
412.20 (b)(2) amended 6648
412.46 (a) revised; (b), (c) and (d) redesignated as (c), (d) and (e); new (b) added; new (c) revised 38527
412.50 (b) revised 38527
412.62 (f)(1) introductory text and (ii) introductory text republished; (f)(1)(ii)(B) and (k) revised 38527

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412.63 (b)(3), (c)(4), (f) and (g) revised; (h), (i) and (j) redesignated as (i), (j) and (k); (b) (4) and (5), (c)(6), and new (h) added; new (j) introductory text and (1) introductory text and (i), and (k) revised 38527

412.70 (c)(5) and (d)(4) revised; (c)(6) and (d)(5) added 38528

412.73 (c)(5) revised; (c)(6) added 38528

412.80 (a)(1) introductory text and (ii) introductory text and (2) revised 38529

412.82 (c) revised; (d) redesignated as (e); new (d) added 38529

412.84 (a) and (g) revised; (h) and (i) redesignated as (i) and (j); new (h) and (k) added; new (j) revised 38529

412.86 Added 38529

412.90 (h) amended 38529

412.92 (a) introductory text and (2) introductory text and (c) introductory text republished; (b)(1) (ii) and (iii), (2), (3) and (4), (e)(3) (i), (ii) and (iii), and (f) redesignated as (b)(1) (iv) and (v), (3), (4) and (5), (e)(3)(i) (A), (B) and (C), and (g) 38529

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412.96 (b) introductory text added; (b)(1) and (d) revised; (e) removed 38531

412.106 (a)(1) introductory text republished; (a)(1)(i) and (2) introductory text, (b)(1) introductory text and (ii), (2), and (c) revised 38531

412.113 (a) revised 1627

(a)(1) and (b) revised 38532

412.116 Added 1627

(a) revised; (d) removed; (e) and (f) redesignated as (d) and (e); new (d) revised 38532

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412.118 Heading and (c) revised; (d)(1) removed; (d)(2) redesignated as (d)(1); new (d)(1) introductory text, (i) and (iii) revised; new (d)(2) added 38532

412.208 (f)(1) introductory text republished; (f)(1)(ii) redesignated as (f)(1)(iii); new (f)(1)(ii) added; (i) revised 38532

412.210 (a)(2), (b), (c) introductory text and (1), (d) introductory text, (1) introductory text and (i), and (e) revised 38533

412.212 (b) (1) and (2) amended 38533

413 Addendum corrected 38835

413.13 Revised 10085

(c)(1)(iii) corrected 12641

413.30 (c) revised 38533

413.35 (d) amended 6648

413.40 (c)(1)(ii) amended 6648

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413.64 (a)(1) heading and (2) and (k) (1) through (6) removed; (a)(1) redesignated as (a); (g) and (h)(1) revised 1628

413.74 (a) and (c) amended 6648

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413.157 (b)(4) redesignated as (b)(5); new (b)(4) added 12017

413.178 Revised 6548

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416.3 (a) amended 6648

416.30 (e) amended 6648

(e) corrected 12945

416.44 (b) and footnote 1 revised 11508

416.110 (c) amended 6648

417.237 (a)(2)(iii) amended 6648

417.532 (a)(2) and (e)(3) amended 6648

417.800 (e) amended 6648

418 Authority citation revised 1628

418.100 (d) revised; (e) removed; (f) through (l) redesignated as (e) through (k); new (f)(2) amended 11508

418.307 Added 1628

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421.3 Revised 17944
421.100 Introductory text republished; (i) added 17944
421.117 Revised 17944
421.128 (f) revised 17945
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424 Added 6634
424.5 (a)(3) corrected 12945
424.7 (a)(2)(i) corrected 12945
424.10 (b) corrected 12945
424.16 (b) heading corrected 12945
424.22 (d)(4) heading corrected 12945
424.24 (c)(3)(ii) corrected 12945
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424.30 Corrected 12945
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424.36 (b)(5) corrected 12945
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424.37 (b) corrected 12945
424.56 (d) Examples 1 and 2 correctly revised 12945
424.60 (a) revised 28388
424.66 Revised 28388
424.66 (d) correctly redesignated as (b); (b) heading correctly revised; (a)(3) corrected 40231
424.82 (c)(3) corrected 12945
424.84 (d) correctly designated and revised 12945
424.124 (a) introductory text and (b) heading corrected 12945
424.352 (b) introductory text corrected 12945

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403.400—403.410 (Subpart D) Added; interim 35333
405—421 (Subchapter B) Heading revised 5358
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405.301—405.376 (Subpart C) Subpart heading and authority citation revised 41733
405.301 Revised 41733

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405.308—405.344 Removed 41733
405.501—405.580 (Subpart E) Authority citation revised 9003
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405.521 (a) and (d)(1) amended; (d)(2) and (3) revised; (e) amended; eff. 10–30–89 40315
405.522 (a) amended; eff. 10–30–89 40315
405.530 Added 9003
405.531 Added 9003
405.532 Added 9003
(a) and (b)(2) corrected 13294
405.533 Added 9003
(b) introductory text corrected 13294
405.550 (b) introductory text and (e)(1) revised; (e) introductory text republished 9004
405.551 Heading, (a), and (f) revised 9004
405.554 Revised 9004
405.555 Heading, (b), and (c)(1) revised; (c) introductory text republished 9005
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405.701—405.750 (Subpart G) Subpart heading revised 41733
405.701 Heading revised; (a), (b), and (c) headings, and (d) added 41733
405.702 Revised 41733
405.704 Revised 41734
405.708 Revised 41734
405.710 Revised 41734
405.715 (b) amended 41734
405.740 (e), (f), and (h) revised 41734
405.1101—405.1137 (Subpart K) Removed 5358
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405.1201—405.1230 (Subpart L) Redesignated as Part 484 and revised; interim 33367
405.1702 (l) redesignated as (m); interim 38679
405.1717 Revised; interim 38679
405.1733 Revised; interim 38679
409.61 (b) amended 4027
409.82 (b) and (c) revised 4026

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409.83 (b) and (c) revised 4026
409.85 (b) and (c) revised 4026
410.68 Added 4026
411 Added 41734
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412.42 (c) introductory text amended 41747
412.84 (k) amended; eff. 10–1–89 36494
412.92 (a) introductory text republished; (a) (1), (2) introductory text, (a)(2)(i), (b)(1)(ii)(B), (e)(3) introductory text, (i), (iii), and (g)(6) amended; (a)(3), (b)(4)(iii) and (e)(3)(iii) revised; eff. 10–1–89 36494
412.94 (b)(1) revised; (b)(4) added; eff. 10–1–89 36494
412.96 (f) revised; eff. 10–1–89 36494
412.106 Revised; eff. 10–1–89 36494
412.113 (b) revised; eff. 10–30–89 40315
412.116 (d) and (e) redesignated as (e) and (f); new (d) added 36495
412.118 (c) (1), (2), (d) (1) and (2) amended; eff. 10–1–89 36495
413 Authority citation revised 37274
413.13 (d) introductory text republished; (d) (3) and (4) revised; (d)(5) added; (f)(2) introductory text republished; (f)(2)(iii)(C) added; eff. 10–30–89 40315
413.85 (a) and (e) revised; eff. 10–30–89 40315
413.86 Added; eff. 10–30–89 40316
413.114 Heading, (a) and (b) revised; (d) added; (eff. 10–10–89) 37274
413.170 (g)(3)removed and reserved; eff. 10–30–89 40319
413.179 Added 5623
416.44 (c) revised 4026
421.5 (f) added 4026
421.100 Introductory text, (a), and (f) revised 4026
421.200 Introductory text and (a) revised 4027
421.204 Removed 4027
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405.501—405.580 (Subpart E) Authority citation revised 32084
405.534 Added; interim 53521
405.535 Added; interim 53521
405.541 Removed 23440
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405.543 Removed 23440
405.544 Removed 23440
405.553 (a), (b)(1)(i), (2) and (c) revised; (d) and (e) added 32084
405.556 (c) amended 9574
405.701 Revised 11020
405.702 Revised 11020
405.704 Revised 11020
405.708 Revised 11021
405.710 Revised 11021
405.715 Republished 11021
405.740 (e), (f), and (h) revised 11021
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405.1310—405.1317 (Subpart M) Removed 9574
405.1702 Regulation at 54 FR 38679 confirmed 11373
405.1717 Regulation at 54 FR 38679 confirmed 11373
405.1733 Regulation at 54 FR 38679 confirmed 11373
405.1890 Removed 2652
405.2102 Amended 9575
405.2120 Revised 23440
405.2121 Heading and introductory text amended 23440
405.2122 Introductory text, (a)(1), (2), (b)(1) introductory text, and (ii) amended 23440
405.2123 Revised 23441
405.2130 Revised 23441
405.2150 Introductory text and (a)(2) table revised; (d) added 18335

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405.2163 (b) revised 9575
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405.2171 (d) revised 9575
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412.25 Nomenclature change; (a) introductory text revised; (a)(13) and (c) added; (b) amended 39820

412.27 Introductory text amended 39820

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412.29 Introductory text amended 39821

412.30 (a) revised; (c) amended 39821

412.32 Removed 39821

412.40—412.52 (Subpart C) Heading revised 39821

412.40 (a) amended 39821

412.42 (a) and (b) introductory text amended 39821

412.46 (d)(1), (e)(1) and (2) amended 39821

412.48 (c) amended 39821

412.50 (a) amended 39821

412.52 Amended 39821

412.60—412.63 (Subpart D) Heading revised 39821

412.60 (a), (b), (c) introductory text, (1), (2) and (3) amended 39821

412.62 Heading, (a), and (j) introductory text revised; (b), (c) introductory text, (d) introductory text and (e) introductory text amended 39821

412.63 Heading, (a)(1), (o) introductory text and (p)(1) revised; (a)(2), (b)(2)(ii) and (n)(1) amended 39822

412.70—412.76 (Subpart E) Heading revised 39822

412.70 Revised 39822

412.71 (b) introductory text republished; (b)(8) revised 33897

Heading and (c)(1) introductory text revised; (c)(2) and (d) amended 39822

412.73 (d)(1), (2) and (e) amended 39822

412.74 Removed 39822

412.75 Heading revised; (b) and (e) amended 39822

412.76 Amended 39822

412.80 (a)(1)(ii)(B) amended 3016

(a)(1)(ii) introductory text republished; (a)(1)(ii)(A) and (c) revised; (a)(2) amended 39822

412.82 (c) revised; (d) removed; (e) redesignated as (d) 39822

412.84 (d) amended 39823

412.90—412.108 (Subpart G) Heading revised 39823

412.90 Revised 39823

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412.92 (b)(1)(iv), (v), (3) and (5) amended; (d) heading, (e)(3) introductory text and (i)(B) revised 39823
412.96 (b)(1) introductory text and (c)(1)(ii) amended; (d) revised 39823
412.98 (a) and (b) revised 39823
412.100 (a) revised 39824
412.102 Introductory text amended 39824
412.104 (a), (b) introductory text, (4) and (5) amended 39824
412.105 Heading, introductory text, (a)(2) and (e) revised; (a) introductory text republished 39824
412.106 (a)(2) and (d)(1) revised; (a)(1)(i), (2)(ii), (d)(2)(i)(B)(*1*) and (*2*) amended 39824
412.108 (c) introductory text and (d)(3) introductory text revised; (a)(1)(i) and (d)(3)(i)(B) amended 39824
412.110—412.130 (Subpart H) Heading revised 39824
412.110 Amended 39824
412.112 Introductory text and (a) revised 39824
412.113 (a)(3) amended 3016
(c) revised 33897
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(a)(2)(i) introductory text republished; (a)(2)(i)(E) revised 39824
412.115 (a) amended 39825
(c) added 47787
412.116 (b)(3)(ii)(B) and (C) amended 3016
412.120 (a) and (b) introductory text amended 39825
412.130 (b)(1) and (2) amended 39825
412.200—412.220 (Subpart K) Heading revised 39825
412.200 Revised 39825
412.204 Revised 39825
412.208 (a), (b) and (h) heading revised 39825
412.210 (a)(1), (b)(3) and (d) introductory text amended 39825
412.212 (a) amended 39825
412.220 Introductory text amended 39825

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412.230 Heading, (a)(1), (3), (4) introductory text, (iii), (e)(1), (2)(i), (ii) introductory text and (A) revised; (a)(4)(v) and (5) added; (d) heading, (1), (3) introductory text and (ii) amended; (e)(2) introductory text republished 39825
412.232 (c), (d)(2)(i) and (ii)(A) revised; (d)(2) introductory text and (ii) introductory text republished 39826
412.234 (b) revised; (c) heading amended 39826
412.273 (a) introductory text, (1) and (b) revised; (c) added 39826
412.278 (f)(1) corrected; (f)(3) correctly designated as (f)(4); (f)(3) added; CFR correction 13046
(f) heading and (g) added; (f)(1) and (3) revised 39826
412.300 (b) revised 39827
412.302 (a), (c)(1)(i)(D), (v), (d)(2) and (3) amended 3016
(b) introductory text, (c)(1)(ii), (iv), (v), (vii)(B) and (2)(i)(B) revised; (b)(3)(iii) and (7) added; (c)(2)(i) introductory text republished 39827
412.302 (c)(1)(v) correctly revised 46510
412.308 (c)(4)(ii) amended 3016
412.320 (a) redesignated in part as (a)(1) and (2); (a) introductory text, (1), (2) and (b)(1) amended 3016
412.324 (b)(2) and (3) amended 3016
412.328 (c)(1) and (f)(1)(iii) amended 3016
(f)(3)(iii) amended 3017
(b)(2), (3), (c)(1), (f)(1)(i) and (iii) revised; (f)(3) introductory text republished; (f)(4) redesignated as (f)(5); (a)(3) and new (f)(4) added 39828
412.331 Added 39828
412.336 (c)(1) amended 3017
412.344 (d)(1) and (2) amended 3017
412.348 (b)(1)(ii) amended 3017
(e)(2) revised 39829
413.1 (b) amended; (f) added 33898
(d)(2) introductory text and (i) revised 39829
413.5 (c) introductory text revised 39829

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413.24 (f)(3)(iii) amended 39829
413.40 (a)(2)(i) introductory text republished; (a)(2)(i)(B), (c)(2), (f)(1)(i) and (g)(3)(iii) revised; (b)(1) amended 39829
413.64 (h)(1)(i) and (ii) amended 39830
413.80 (a) revised; (h) added 33898
413.86 (h)(6) added 39830
413.118 (d)(3) redesignated as (d)(4); (d)(2) and new (d)(4) introductory text revised; new (d)(3) added 36017
(d)(4) corrected 45113
413.122 (b)(4) added 36017
413.124 Added 36017
413.130 (a)(3), (10) and (f) amended 3017
(j) added 36017
(b)(4), (5) and (6) redesignated as (b)(5), (6) and (7), (b)(1), (2), and new (b)(5) revised; new (b)(4), (8) and (9) added; new (b)(6)(i) amended; eff. 10–23–92 43917
413.134 (f)(2)(iii)(D) amended 3017, 39830
(a) introductory text republished; (g)(3) and (h) through (k) redesignated as (g)(4) and (i) through (l); (a)(2), (b) heading, (1), (f)(1), (4), (g)(2), new (g)(4) and new (j) revised; (b)(8), (9), new (g)(3) and (h) added; eff. 10–23–92 43919
413.157 (c)(5) removed 39830
414 Authority citation revised 42493, 57688
414.1—414.60 (Subpart A) correctly redesignated from 415.1—415.60 Subpart A 42492
414.2 Corrected 42492
414.22 (a)(2) corrected 42493
414.24 (c)(2) corrected 42492
414.26 (a)(1), (2) and (3) corrected 42492
414.28 (a) and (b) corrected 42492
414.38 (c) and (d) corrected 42492
(b) corrected 42493
414.42 Correctly revised 42493
414.46 (b)(1) and (f)(1) corrected 42492
414.56 (b) corrected 42493
414.58 (a) corrected 42492
414.60 Corrected 42492

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414.200 Added 57689
414.202 Added 57689
414.210 Added 57689
414.220 Added 57689
414.222 Added 57690
414.226—414.229 (Subpart D) Added 57688
414.226 Added 57690
414.228 Added 57691
414.229 Added 57691
414.230 (f) revised 57111
414.232 Added 57688, 57692
414.330 Added 54187
414.450—414.453 (Subpart H) Added 33898
416 Authority citation revised 7135
415.1—415.60 (Subpart A) correctly designated as 414.1—414.60 subpart A 42492
416.42 (b) revised 33899
416.49 Revised 7135
416.61 (a)(8) added; (b) amended 33899
417 Authority citation revised 7135, 8201, 24981
417.107 (i) revised 7135
417.416 (d)(1) revised 24981
417.436 (a) introductory text republished; (a)(6) redesignated as (a)(7); (a)(5) and new (a)(7) revised; new (a)(6) and (d) added; interim 8201
417.472 (f) redesigned as (g); new (f) added; interim 8202
417.800 (b) revised 7135
417.801 (b) introductory text republished; (b)(5) redesignated as (b)(6); (b)(4) and new (b)(6) revised; (b)(5) added; interim 8202
418 Authority citation revised 7135
418.1 (c) revised 36017
418.21 (a) revised 36017
418.22 (a)(1) revised 36017
418.92 Revised 7135
420 Authority citation revised 24982, 27306
420.200—420.206 (Subpart C) Heading revised 27306
420.200 Revised 27306
420.201 Amended 24982, 27306
Corrected 35760
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420.205 Revised 27306
420.206 (a) introductory text republished; (a)(1), (3), (b)(2), (3) and (c) revised 27306
421 Authority citation revised 27307
421.1 (a) revised 27307
421.200 Introductory text revised 27307
421.202 Introductory text and (c) revised 27307
421.210 Added 27307
424.1 (c) revised 24982
424.40 (c)(3) revised 24982
424.57 Added 27308

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400.202 Amended 30666
401 Authority citation revised 61837
401.126 (b)(2) revised 61837
401.133 Heading revised; (d) and (e) added 61838
403.400—403.410 (Subpart D) Removed 54049
405.480 (a) introductory text, (1), (2) and (3) revised 63686
405.502 Regulation at 57 FR 36013 confirmed 58505
405.550—405.580 (Subpart F) Authority citation revised 63686
405.550 (a) and (e)(1) amended; (c) revised 63686
405.551 (a) amended 63686
405.556 Regulation at 57 FR 36014 confirmed 58505
406.21 Regulation at 57 FR 36014 confirmed 58505
406.23 Regulation at 57 FR 36014 confirmed 58505
406.32 Regulation at 57 FR 36014 confirmed 58505
406.33 Regulation at 57 FR 36014 confirmed 58505
409.5 Amended 30666
409.10—409.19 (Subpart B) Heading revised 30666
409.10 (a)(3) amended; (a) introductory text and (b) revised 30666

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409.11 (b)(1)(ii) and (3) introductory text amended; (b) heading, (1)(iii) and (3)(ii) revised 30666
409.12 (b) amended 30666
Heading and (a) revised 30667
409.13 (a) introductory text, (1), (2), (3) and (b) amended 30666
409.14 (a) introductory text, (1), (2), (b) introductory text, (1) and (2) amended 30666
409.15 Introductory text amended 30666
409.16 Introductory text, (a), (b) and (c) amended 30666
409.20 (a) introductory text revised; (c)(3) added 30667
409.27 Revised 30667
409.30 Introductory text, (a)(2), (b)(1) and (2) amended 30666
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409.31 (b)(2)(i) and (ii) amended 30666
409.40 Regulation at 57 FR 36014 confirmed 58505
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409.61 (a)(2) and (c) amended 30666
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409.64 (a)(2)(ii) amended 30667
409.65 (a)(1), (3), (4), (d)(1), (2), (e)(1), (2) introductory text, (i) and (ii) amended 30666
(d)(3) revised 30667
409.66 (b) and (c)(2) amended 30666
409.68 Heading, (a) introductory text, (1) through (4), (b)(2) and (c) amended 30666
409.80 (a)(1) and (2) amended 30666
409.82 (c) amended 30666
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(a)(1) revised 30667
409.87 (a)(3) amended 30666
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409.97 Regulation at 57 FR 36014 confirmed 58505
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410.32 (b)(1) amended 30668
410.36 Regulation at 57 FR 36015 confirmed 58505
410.38 (b) revised 30668
410.40 (a), (b)(3)(i), (c)(1), (2), (3), (e)(1), (2), (3) amended; (b)(3) introductory text revised 30668
410.60 (b) and (d) revised 30668
410.62 (b) and (c) revised 30668
410.150 (a)(2) revised; (b)(12) added 30668
410.152 (a) heading and (2) introductory text revised; (k) added 30668
410.155 (b) amended 30668
410.161 (b)(2) amended 30668
411.15 (m) revised 30669
Regulation at 57 FR 36015 confirmed 58505
411.60 Regulation at 57 FR 36015 confirmed 58505
411.62 Regulation at 57 FR 36015 confirmed 58505
412 Authority citation revised 30669
412.1 (a) amended 46337
412.2 (b)(2)(i) revised; (f)(8) amended 46337
412.25 (a)(1) revised; (d) added 46337
412.62 (c)(2) amended 46337
412.63 (c)(2)(i), (g) introductory text, (j) introductory text and (k) introductory text amended; (n), (o) and (p) redesignated as (q), (r) and (s); new (n), (o) and (p) added; (l), (m) and new (s)(2) revised 46337
412.70 Amended 46338
412.73 (c)(1) amended; (c)(9) revised; (c)(10), (11) and (12) added 46338
412.75 (d) amended 46338
412.90 (j) added 30669
412.96 (g)(2) amended 46338
412.98 (b) amended 46338
412.102 Revised 46338
412.105 (g)(1)(ii), (iii) and (2)(v) revised 46338
412.108 (a)(1) and (2) amended; (c) revised 46339
(c)(2)(i) and (ii) corrected 67350
412.109 Added 30669
412.113 Regulation at 57 FR 36016 confirmed 58505

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412.115 (b) amended 46339
412.230 (e)(2)(ii)(B) revised 46339
412.232 (b) and (d)(2)(ii)(B) revised 46339
412.234 (b) revised 46339
412.308 (b) revised 46339
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413 Authority citation revised 30670, 46340
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413.13 (c)(2)(iv) added 30670
413.40 Revised 46340
413.70 Added 30670
413.86 (e)(3) revised; (b), (g)(1) and (h)(2) amended 46343
413.114 Heading revised; (b) amended 30671
413.118 Regulation at 57 FR 36017 confirmed 58505
413.122 Regulation at 57 FR 36017 confirmed 58505
413.124 Regulation at 57 FR 36017 confirmed 58505
413.130 (b)(4) introductory text amended 17528
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413.134 (b)(8), (f)(4), (h)(3) introductory text and (3)(i) amended 17528
414.1—414.60 (Subpart A) Authority citation revised 63686
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414.224 (a) revised 34919
417 Authority citation revised 38067
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417.1 Amended 38067
417.101—417.109 (Subpart B) Heading revised 38068
417.101 Amended 38077
417.102 (a) and (b) amended 38082
(a) and (b) amended 38083
417.103 (a)(3)(ii)(C), (c)(2), (e)(1), (2) and (3) amended 38082

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(a)(1), (3), (b) introductory text, (d) and (e) introductory text amended 38083

417.104 (a)(4), (b)(1), (2)(i), (4)(ii) and (c)(2) amended 38082

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417.105 (a) and (b) amended 38082

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417.107 Removed 38068

417.108 Redesignated as 417.168 38068

417.109 Redesignated as 417.169 38068

417.120—417.126 (Subpart C) Added 38068

417.140 Revised 38070

417.141 Revised 38070

417.142 Revised 38070

417.143 (b)(2) and (g) amended 38077

417.144 (a) through (e) amended 38077

417.150 Amended 38077

417.151 Amended 38077

417.152 Amended 38077

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417.154 Amended 38077

417.155 (a) through (e) and (g) amended 38077

417.156 Introductory text, (a), (b) and (c) amended 38083

417.157 Amended 38077

417.158 Amended 38082

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417.159 Amended 38078

417.160—417.166 (Subpart F) Heading revised 38071

417.160 Revised 38071

417.161 Revised 38071

417.162 Revised 38071

417.163 Amended 38078

417.164 Heading, (a), (b) and (c) amended 38078

417.165 Amended 38078

417.168 Redesignated from 417.108 38068

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417.169 Redesignated from 417.109 38068

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417.400 (b) amended 38078

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417.406 Heading, (a)(2), (3) and (b)(2) amended 38078

417.407 Heading, (a), (b) and (c) amended 38078

417.408 Amended 38078

417.410 Amended 38078

417.412 (b) amended 38082

417.413 (a), (b) heading, (1) through (4), (c), (d)(1) through (7), (e)(1) and (2) amended 38082

417.414 Amended 38078

417.416 (a), (c), (d)(1), (2), (e)(1) and (2) amended 38082

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417.420 Amended 38078

417.422 Heading, (a), (b) and (c) amended 38078

417.424 Amended 38078

417.426 (a), (b) and (c) amended 38079

417.428 (a) introductory text, (1), (4), (b) introductory text, (1), (2), (3), (5) and (c) amended 38082

417.430 (a)(1), (2), (b) introductory text, (3), (4)(i), (ii), (6) introductory text, (i), (ii), (7) and (8) amended 38082

417.432 (a), (b), (c) and (e) amended 38082

417.434 Amended 38082

417.436 Revised 38072

417.440 Amended 38079

417.442 Heading, (a), (b) introductory text and (2) amended 38082

417.444 Revised 38073

417.448 Amended 38079

417.450 (a), (b) and (c) amended 38079

417.452 Amended 38079

417.454 (a) and (b) amended 38082

417.456 Amended 38079

417.458 Introductory text, (a), (b) and (c) amended 38082

417.460 Revised 38073

417.470 (a) and (b) introductory text amended 38079

417.472 Amended 38079

417.474 (b) amended 38082

417.478 Introductory text, (c) and (d) amended 38079

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417.480 Heading, introductory text, (b)(1) and (7) amended 38082
417.481 Heading and introductory text amended 38082
417.482 Introductory text, (b), (c), (e), (f)(1) and (2) amended 38082
417.484 (a) introductory text, (1), (3) and (b) amended 38082
417.486 Introductory text amended 38082
417.488 Introductory text amended 38082
417.490 Amended 38082
417.492 Amended 38079
417.494 Amended 38079
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417.523 Amended 38079
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417.528 Amended 38080
417.530 Amended 38080
417.531 (a), (b) introductory text and (1) amended 38082
417.532 (a)(1), (2), (3), (4), (b) heading, (3), (c) introductory text, (2), (e) heading, introductory text, (1), (f), (g) and (h) amended 38082
417.533 Introductory text and (a) amended 38082
417.534 (a) and (b) amended 38082
417.536 Amended 38080
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417.540 Heading, (a) and (b) amended 38082
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417.550 Amended 38080
417.552 (a) amended 38082
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417.556 Heading and (a) through (d) amended 38082

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417.558 Heading, (a), (b) heading, (1) and (2) amended 38082
417.560 (a) introductory text, (b), (c), (d) introductory text, (1) and (2) amended 38082
417.562 (a), (b)(3), (c) introductory text and (d) amended 38082
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417.568 (a)(1), (b)(1), (c), (d) and (e) amended 38082
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417.574 (a) and (b) amended 38082
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417.580 (a) and (b) amended 38080
417.582 Amended 38080
417.584 Heading, introductory text, (a), (b)(2) and (d) amended 38082
417.585 (a), (b) introductory text, (1) and (c) amended 38082
417.586 Heading, (a) heading, (1), (2), (3), (b)(1), (c) heading, (1), (d), (e) introductory text, (1) and (2) amended 38083
417.588 (b), (c)(1), (2) and (3) amended 38083
417.590 Revised 38075
417.592 Amended 38080
417.594 Amended 38080
417.596 (a), (b), (c)(1), (2), (3) and (d)(2) amended 38083
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417.616 (a)(1), (c)(1) and (2) amended 38083
417.618 Amended 38083
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417.634 Amended 38083
417.636 (a) and (b) amended 38083

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417.662 (a) amended 38083
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417.670 (c) revised 38081
417.800 (b)(1)(iii) and (c)(1) amended 38081
417.801 (a)(2), (b)(2) and (d)(1)(iii) amended 38081
417.802 (a) amended 38081
417.806 (a) amended 38081
417.810 (c)(2) amended 38081
417.910 Revised 38076
417.911 Revised 38076
417.912 Amended 38081
417.913 Amended 38081
417.915 (a) amended 38083
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417.917 Introductory text amended 38081
417.918 (a) amended 38081
417.919 (a) and (b) amended 38083
417.920 Revised 38076
417.921 Amended 38081
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417.923 (a), (b), (d) introductory text, (e), (f)(1) and (4) amended 38081
417.924 (a)(1), (2), (3), (b)(1), (3) and (4) amended 38081
417.925 Heading revised; (a) introductory text, (1) and (b) amended 38081
417.926 (a) and (c) amended 38082
417.930 Revised 38077
417.931 Removed 38077
(a) introductory text and (b) amended 38082
417.932 Heading revised; (a) and (b) amended 38082
417.933 Heading revised 38082
417.934 Amended 38083
417.935 Heading revised; introductory text amended 38082
417.936 Amended 38082
417.937 (a), (b) and (c) amended 38082
418.1 Regulation at 57 FR 36017 confirmed 58505

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418.21 Regulation at 57 FR 36017 confirmed 58505
418.22 Regulation at 57 FR 36017 confirmed 58505
421.210 (e)(2) revised; (e)(3) and (4) added 60796
421.212 Added 60797
424.15 Added 30671
424.20 Introductory text amended 30671
424.350 Revised 65129
424.352 Revised 65130
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400.202 Amended; interim 6576
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400.310 Revised (OMB numbers) 39297
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401.130 (b)(17) revised 56232
401.133 Regulation at 58 FR 61838 eff. date corrected to 2–22–94 108
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403.500—403.512 (Subpart E) Authority citation revised 51128
403.500 Revised 51128
403.501 Added 51129
403.502 Revised 51129
403.504 Revised 51129
403.506 Removed 51129
403.508 Revised 51129
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405 Technical correction 36069, 39828
405.501—405.535 (Subpart E) Authority citation revised 49832
405.512 (c)(8) revised 10298
405.534 (b) introductory text, (2), (3), (c) introductory text, (2), (3), (d) introductory text, (2) and (3) revised 49833
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405.701—405.750 (Subpart G) Authority citation revised 12181
405.701 Heading revised; (d) added 12181
405.740 Revised 12181
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405.801—405.874 (Subpart H) Heading revised 12182
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405.802 Revised 12182
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405.815 Redesignated from 405.820 and revised 12182
405.817 Added 12182
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405.821 Revised 12183
405.822 Heading amended 12183
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405.824 Heading amended 12183
405.825 Heading amended 12183
405.826 Heading amended 12183
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405.1413 (a)(1) amended 64152
405.1720 Introductory text correctly revised; CFR correction 18318
405.2100—405.2184 (Subpart U) Authority citation revised 46513
405.2137 Regulation at 56 FR 43709 confirmed; (b)(7) revised 1284
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405.2163 Regulation at 56 FR 43709 confirmed; (g) revised; (h) added 1284
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405.2170 Introductory text amended; interim; eff. 10–11–94 46514
405.2171 Heading, introductory text and (e) revised; (a) and (d)(1) amended; interim; eff. 10–11–94 46514
405.2401—405.2472 (Subpart X) Authority citation revised 26958

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405.2401 (b) amended 26958
406 Authority citation revised 26959
406.32 (b)(3) and (c) through (f) redesignated as (b)(4) and (d) through (g); new (b)(3) and new (c) added; new (b)(4) revised 26959
408.20 (b) heading, (1) introductory text, (2), (c) heading and introductory text revised; (b)(3) added 26959
409 Authority citation revised 65493
409.32 (a) revised 65493
409.40 Revised 65493
409.41 Revised 65494
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409.44 Revised 65494
409.45 Added 65495
409.46 Redesignated as 409.50; new 409.46 added 65496
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410 Authority citation revised 6576, 26959, 49833, 63462
410.1 (a) amended 63462
410.2 Revised; interim 6577
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410.3 (a)(2) amended; interim 6577
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410.10 Regulation at 56 FR 43709 confirmed 1284
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410.29 Regulation at 56 FR 43709 confirmed 1284
410.34 Introductory text removed; (b)(1) through (6) redesignated as (d)(1) through (6); heading, (a) and new (d)(1) revised; new (d) heading, new (b) and new (c) added 49833
410.43 Added; interim 6577
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410.150 (a)(2) revised; (b)(13) added; interim....6577
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412.60 (d)(2) amended....45397
412.63 (m)(1), (r) heading, (1) introductory text, (i), (2) introductory text, (i), and (s)(2) revised....45397
412.71 (b) introductory text revised; (b)(1) removed; (b)(2) through (8) redesignated as (b)(1) through (7)....45398

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412.84 (j) amended....45398
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413.53 (a)(1)(i) revised 45401
413.56 Removed 45401
413.64 (h)(2) through (6) and (h)(1)(i) through (iv) redesignated as (h)(3) through (7) and (h)(2)(i) through (iv); new (h)(1) revised; new (h)(2), (v) and (vi) added 36713
413.86 (f)(1)(ii) and (g)(1) introductory text amended 45401
413.123 (b) revised 49834
413.124 (a) revised 26960
413.125 Added 65497
413.130 (j)(1)(ii) revised 26960
413.134 (d)(1) amended; (e)(1) and (2)(ii) revised; (e)(2)(iii), (iv) and (4) added 45401
413.153 (d)(2) revised; (d)(3) added 45402
413.157 (b)(3) revised 26960
413.170 Regulation at 56 FR 43709 confirmed 1284
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413.174 (b)(4)(iv) revised 45402
414 Technical correction 36069, 39828
414.1—414.60 (Subpart A) Authority citation revised 63463
414.2 Amended 63463
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414.300 Regulation at 56 FR 43710 confirmed 1284
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414.314 (c) revised; (d) removed 63463
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417 Authority citation revised 36083, 49836, 59941
417.124 (e)(4) added; eff. 10–31–94 49843
417.140 Heading and text revised; eff. 10–31–94 49836
417.141 Removed; eff. 10–31–94 49836
417.142 Revised; eff. 10–31–94 49836
417.144 Heading and text revised; eff. 10–31–94 49837
417.150 Amended; eff. 10–31–94 ..... 49837, 49843
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417.152 Heading and text revised; eff. 10–31–94 49838
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417.154 Revised; eff. 10–31–94 49839
417.155 Heading and text revised; eff. 10–31–94 49840
417.156 Revised; eff. 10–31–94 49841
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417.159 Revised; eff. 10–31–94 49841
417.160—417.169 (Subpart F) Heading revised; eff. 10–31–94 49841
417.160 Heading and text revised; eff. 10–31–94 49841
417.163 Revised; eff. 10–31–94 49841
417.164 Heading and text revised; eff. 10–31–94 49842
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417.169 Removed; eff. 10–31–94 49842
417.400 (a) amended; eff. 10–31–94 49843
417.436 (a)(11) amended; eff. 10–31–94 49843
417.440 (f) added 59941
417.454 (b) redesignated as (c); (a) heading, new (b) and (c) heading added 59941
417.460 (a)(11) heading revised; eff. 10–31–94 49843
417.500 Added 36083
417.600 Amended 59941
417.604 (a) and (b) revised 59941
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417.606 Revised 59942
417.608 Heading, (a) and (c) revised 59942
417.610 Heading, introductory text and (b) revised 59942
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417.618 Amended 59942
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417.801 (b)(2) amended; eff. 10–31–94 49843
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417.834 Added 59943
417.836 Added 59943
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417.910 Heading and text revised; eff. 10–31–94 49842
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417.913 Removed; eff. 10–31–94 49842
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417.915 Removed; eff. 10–31–94 49842
417.916 Removed; eff. 10–31–94 49842
417.917 Removed; eff. 10–31–94 49842
417.918 Removed; eff. 10–31–94 49842
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417.921 Removed; eff. 10–31–94 49842
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417.923 Removed; eff. 10–31–94 49842
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417.925 Removed; eff. 10–31–94 49842
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417.932 Removed; eff. 10–31–94 49842
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417.936 Removed; eff. 10–31–94 49842
417.937 Revised; eff. 10–31–94 49842
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418 Authority citation revised 26960, 65497
418.202 (g) revised 65498
418.306 (b)(2) revised; (b)(3) added 26960
418.307 Revised 36713
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421.112 (b) amended 682
421.118 (b) amended 682
421.122 Revised 682
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421.201 Added 682
421.203 Added 682
424 Authority citation revised 10298
424.3 Amended 10299
424.32 (a) revised 10299
424.34 (b)(4) revised 10299
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401.601—401.625 (Subpart F) Authority citation removed 50441
403 Authority citation added 50441
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405.201—405.215 (Subpart B) Added; eff. 11–1–95 48423
405.465—405.482 (Subpart D) Removed 63175
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405.500—405.535 (Subpart E) Authority citation revised 63175
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405.502 (a)(10) amended 63188
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405.1737 Redesignated as 486.163 2326
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405.2150 (b) removed; (c) and (d) redesignated as (b) and (c); introductory text, (a) and new (c)(1) revised; eff. 10–18–95 48044
405.2400—405.2472 (Subpart X) Authority citation revised 63176
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405.2401 (b) amended 63176
405.2468 (b)(1) revised 63176
406 Authority citation revised 50441
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410.34 (a)(1) revised 14224
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410.60 (a)(3)(ii) amended 2329
411 Authority citation revised 41978, 45361, 50441
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411.33 (a) heading and introductory text revised; (a)(1), (3), (b) introductory text, (3) and (e) heading amended; (c) and (d) removed 45362
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411.161 Added 45368
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411.162 Heading and (a) revised; (b)(2)(i), (ii), (c)(2)(iii), (iv), (3)(i), (ii), (4) introductory text, (i), (ii), (d)(9), (10) and (f) amended; (e) removed 45368
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411.170 (a) revised; (b), (d), (e) and (f) removed 45370
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411.172 Heading, (c), (d) introductory text and (e) amended; (a), (b) and (d) revised; (g) added 45370
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411.406 (e) revised; eff. 11–1–95 48425
412 Authority citation revised 50441
412.4 (d)(1) amended 45846
412.23 (e)(2) and (3) revised; (e)(4) amended 45846
412.29 (a) revised 45847
412.30 (b) and (c) redesignated as (c) and (d); (a) and new (c) revised; new (b) added; new (d) amended 45847
412.46 Revised 45847
412.50 (a) and (b) amended 63188
412.63 (s)(5) added 45847
412.71 (c)(1)(i) amended 63188
412.92 (b)(5) amended 45848
412.96 (c)(2)(ii) amended 45848
412.105 (b) revised 45848
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412.106 (b)(3) revised 45848
412.109 (b) through (e) redesignated as (c) through (f); (a), new (c)(1), (2)(ii), (d) introductory text, (1), new (e) heading and (1) revised; new (b) added 45848
412.130 (a)(3) amended 45848
412.230 (a)(1) revised; (a)(5) added 45848
412.232 (a)(4) added 45849
412.234 (a)(4) added 45849
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412.308 (b)(3) added; (c)(1)(ii) revised 45849
412.328 (e)(4) added 45849
413 Authority citation revised 33135, 45849
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413.5 (c)(9) amended 63189
413.13 (g)(1)(i) amended 63189
413.24 (f)(4)(ii) revised; (f)(4)(iii) amended 33125
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(d) introductory text and (h) revised 37594
413.30 (e) revised; (f) introductory text amended; (f)(5), (6), (7) and (9) removed; (f)(8) redesignated as (f)(5) 45849
413.35 (b)(2) amended 45849
413.40 (c)(2) and (g)(1) amended; (e)(1) revised 45849
413.70 (b)(2)(i) amended 45850
413.80 (h) amended 63189
413.86 (b)(1) and (g)(1)(ii) amended 63189
413.100 Added 33136
413.174 (b)(4)(iv) amended 63189
413.300—413.321 (Subpart I) Added 37594
414 Authority citation revised 35497, 50442
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414.22 Amended 50442
414.24 Heading and (c)(2) amended 50442
414.28 Amended 53877
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414.30 Amended 50442
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414.32 Heading and (b) amended 50442
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414.39 (b)(2) corrected 49, 36733
414.40 (b) introductory text amended 50442
414.44 (a)(1), (b) introductory text, (d), (e) and (f) amended 50442
414.46 (a)(1), (e) and (g) amended; (b), (c) and (d) revised 63177

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414.58 Heading and (a) amended 50442
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414.220 (a), (b), (f)(3) introductory text, (i) and (ii) revised; (f)(4) and (g) added 35497
414.222 (a) revised; (e) added 35497
414.228 (b)(2)(ii) revised; (b)(2)(iii) and (iv) added 35498
414.229 Heading and (c)(3) revised 35498
414.232 (a) revised 35498
414.450—414.453 (Subpart H) Removed 63178
415 Added 63178
416 Authority citation revised 50441
417.1 Amended 34887, 45674
417.2 (a) amended 45675
417.400 Revised 45675
417.401 Amended 45675
417.404 Revised 45675
417.406 Revised 45675
417.407 Revised 45675
417.408 (a) redesignated in part as (a)(1) and (2); (a)(2), (b)(1) and (c) introductory text amended 45676
417.410 Heading revised; (a) heading, (b) heading, (c) heading, (d) heading, (e) heading and (f) heading added 45676
417.412 (a) and (b) designation removed; (b)(1) and (2) redesignated as (a) and (b) 45676
417.413 (b) introductory text, (1), (2), (c), (d)(2)(i), (3), (5) and (6) revised 45676
417.414 (b)(1) amended; (b)(4) removed 45677
417.416 (b) and (d) revised 45677
417.420 (b) and (c)(1) amended 45677
417.422 (a) designation, (b) and (c) removed; (a)(1) through (7) redesignated as (a) through (g) 45677
417.423 Added 45677
417.424 (b) redesignated in part as (b)(1) and (2); new (b)(2) amended 45677
417.426 (b)(2) and (c) revised 45677
417.428 (c) amended 45677

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417.430 (b)(3) revised; (b)(6)(i) amended 45677
417.432 (e) heading revised 45677
417.436 (d)(1)(i), (ii), (vii) and (2)(ii) revised; (d)(3) added 33292
417.440 (b)(1), (c) and (d) introductory text revised 45678
417.442 Heading and (a) revised 45678
417.450 (c) revised 45678
417.452 (a)(1), (2) and (b) introductory text amended 45678
417.454 (a) heading revised 45678
417.456 (f) amended 45678
417.458 Introductory text amended 45678
417.460 Revised 45678
417.461 Added 45679
417.464 Added 45680
417.472 (a) and (b) revised 45680
417.474 Revised 45680
417.476 Revised 45680
417.480 Heading and introductory text revised 45680
417.481 Heading and introductory text revised 45680
417.486 Introductory text, (a)(1), (b) and (c) amended; (d) revised 45680
417.488 Revised 45680
417.492 (a)(1)(iii) and (b) revised 45681
417.494 (a)(3), (b)(1)(iv), (2), (4), (c)(4) and (5) revised 45681
417.500 (a) introductory text, (3) and (4) amended; (b) heading revised; (b)(1) heading and (2) heading added 45681
417.520 Revised 45681
417.521 Removed 45681
417.522 (a) introductory text and (3)(iii) amended 45681
417.523 (a) heading revised; (a) and (b)(2) amended 45681
417.524 Revised 46229
417.526 Amended 46229
417.528 Heading, (a), (b) and (c) revised; (d) heading added 46229
417.530 Revised 46230
417.531 (a) and (b) introductory text amended 46230
417.532 Amended; (a)(4) removed; (g) revised 46230
417.533 Introductory text, (a), (b) and (c) amended 46230

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417.536 Heading and (m) heading revised; (a), (f)(3) and (m) amended 46230
417.538 (a), (b) heading and (d) heading revised; (d) amended 46230
417.544 (a) designated in part as (a)(1), (2) and (3); (b) designated in part as (b)(1) and (2) 46230
417.546 (a) designation, (b) and note removed; (a)(1) and (2) redesignated as (a) and (b); (b) note removed 34887
(a) corrected 45372
417.548 (a) and (b) amended 46230
417.550 Revised 46230
417.552 (a) introductory text and (1) amended 46230
417.554 Amended 46231, 63189
417.558 Revised 46231
417.560 (d)(1) amended; (d)(2) removed 34888
(a) introductory text and (d)(1) amended; (d)(2) removed 46231
417.562 Removed 34888
417.564 Revised 46231
417.568 (a)(1), (2), (b)(2), (3) and (d) amended; (c) revised 46231
417.576 (b)(2)(i) revised 34888
(b)(2)(ii), (c)(1), (2)(ii), (d) heading, introductory text, (1), (2) and (e)(1) amended; (b)(3) and (e)(3) revised 46231
417.580 (a) amended 46231
417.582 Amended; heading revised 46232
417.584 Introductory text and (c) revised; (d) amended 46232
417.585 Heading revised; (a), (b) introductory text, (2) and (c) amended 46232
417.586 Removed 46232
417.588 (a) and (c)(2) amended 46232
417.592 Revised 46232
417.594 (a), (b)(1), (2), (c), (d) and (e) revised 46232
417.596 (a), (b), (c)(1), (2) and (d) amended 46233
417.597 (a) introductory text amended 46233
417.598 Amended 46233
417.600 Revised 46233
417.602 Amended; heading revised 46233

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417.604 Revised 46233
417.628 Removed 46234
417.632 (c) and (d) revised 46234
417.644 (a) and (c) amended 46234
417.648 Revised 46234
417.652 Amended 46234
417.656 Revised 46234
417.666 Amended 46234
417.668 Amended 46234
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417.676 (a) through (d) amended 46234
417.678 Amended 46234
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417.682 (a) and (c) amended 46234
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417.690 (a) and (b) amended 46234
417.692 (c)(1) and (2) amended 46234
417.694 Amended 46234
417.800 Heading and (c)(2) revised 34888
418 Authority citation revised 50441
420 Authority citation revised 50442
420.200 Amended 50442
421 Authority citation revised 50442
421.1 (a) revised; (b) redesignated as (c); new (b) added 50442
421.120 Correctly added; CFR correction 21048
424 Authority citation revised 38271, 50442
424.1 (b)(1) revised 38271
(a) revised 50442
424.5 (a)(4) revised 38271
424.10—424.27 (Subpart B) Heading revised 38271
424.10 Revised 38271
424.11 (b) and (e) introductory text revised; (e)(4), (5) and (6) added 38272
424.15 (a) revised 45850
424.20 Introductory text and (e) revised 38272
424.57 (c) revised 63444

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401.601 (d)(2)(ii) revised; eff. 10–21–96 49271
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405.350 Introductory text revised; eff. 10–21–96 49271
405.356 Revised; eff. 10–21–96 49271
405.357 Added; eff. 10–21–96 49271
405.358 Added; eff. 10–21–96 49271
405.701—405.750 (Subpart G) Authority citation revised 32348
405.718 Introductory text amended 32348
405.718a (b)(4) amended 32348
405.718c (a)(2)(ii) amended 32348
405.718e Amended 32348
405.724 Amended 32348
405.730 Amended 32348
405.750 Heading and (b) introductory text amended 32348
405.815 Amended 32348
405.2163 (f) amended 19743
405.2401 (b) amended 14657
405.2430 (a)(1)(iii) revised 14657
405.2446 (b) revised 14657
405.2448 (b)(1) through (5) and (7) through (18) amended; (b)(6) and (19) revised; (b)(20) redesignated as (b)(21); new (b)(20) added 14657
405.2450 (a) introductory text and (a)(1) revised 14657
405.2463 Added 14657
405.2466 (b)(1)(iv) added 14657
405.2468 (b)(1), (3) and (d)(2) revised 14658
406.6 (b) revised 40345
406.12 (b) introductory text revised; (b)(1) amended; (b)(3) added; Footnote 1 removed 40345
406.21 (e) removed 40345
406.24 Added 40346
407.20 Revised 40346
407.25 (c) revised 40347
408.24 (a)(6), (7), (8) and (b)(2)(i) revised; (a)(9) added 40347
412.63 (s)(1) amended; eff. 10–29–96 46224
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412.105 (d) correctly added 2725
(g)(1)(i)(D) added; eff. 10–29–96 46224
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412.109 (c) revised; (f) redesignated as (g); new (f) added 21972
412.246 (b) revised; eff. 10–29–96 46224

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412.302 (d)(1) revised; (d)(4) added; eff. 10–29–96 46224

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413 Authority citation revised 37014

413.40 (g)(1) corrected 2725

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413.86 (b) and (g)(1) introductory text amended, (b)(4), added; eff. 10–29–96 46225

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413.153 (b)(4) and (f) added 37014

414.30 (b)(3) correctly revised; (c) correctly removed 42385

415.178 (b) correctly added 42385

416.35 (b)(1)(i) and (d) introductory text amended 40347

417 Authority citation revised 13446

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417.151 (a) and (e) revised 27287

417.152 Removed 27287

417.153 Heading and (a) revised 27287

417.154 Removed 27287

417.155 (d)(2) introductory text amended 27288

417.157 Revised 27287

417.159 Amended 27288

417.164 Heading amended 27288

417.166 (a)(1) amended 27288

417.479 Added 13446

(a) introductory text, (b), (c), (d), (g) introductory text, (1)(i), (2)(ii) introductory text, (iii), (h)(1) introductory text, (v)(B), (2)(i) introductory text, (ii) introductory text, (3) introductory text, (i)(1) introductory text, (2) introductory text and (j) corrected 46385

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417.500 (a)(9) added 13448

417.634 Amended 32348

417.636 (a)(1), (b) heading and introductory text amended 32348

417.638 Amended 32348

417.830 Amended 32348

417.840 Amended 32348

417.912 Removed; CFR correction 38395

417.913 Removed; CFR correction 38395

417.914 Removed; CFR correction 38395

417.915 Removed; CFR correction 38395

417.916 Removed; CFR correction 38395

417.917 Removed; CFR correction 38395

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417.919 Removed; CFR correction 38395

417.921 Removed; CFR correction 38395

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417.924 Removed; CFR correction 38395

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417.926 Removed; CFR correction 38395

417.932 Removed; CFR correction 38395

417.933 Removed; CFR correction 38395

417.935 Removed; CFR correction 38395

417.936 Removed; CFR correction 38395

421.214 Added; eff. 10–21–96 4927

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